

EPA Jacket 54382-3

Vol.2



Please read instructions on reverse before completing form

Copy to Maureen Skerch PA 3/9/5

Form Approved. OMB No. 2070-0060

		United States Environmental Protection Agency Washington, DC 20460		<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other		OPP Identifier Number	
Application for Pesticide - Section I							
1. Company/Product Number 54382-3		2. EPA Product Manager Akiva Abramovitch		3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted			
4. Company/Product (Name) Intervet Inc./Taktic Emulsifiable Concentrate Miticide/Insecticide		PM# 4					
5. Name and Address of Applicant (Include ZIP Code) Intervet Inc. 29160 Intervet Lane Millboro, DE 19966 <input checked="" type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____					
Section - II							
<input type="checkbox"/> Amendment - Explain below.		<input type="checkbox"/> Final printed labels in response to Agency letter dated _____		NOTIFICATION			
<input type="checkbox"/> Resubmission in response to Agency letter dated _____		<input type="checkbox"/> "Me Too" Application.		MAR 21 2005			
<input checked="" type="checkbox"/> Notification - Explain below.		<input type="checkbox"/> Other - Explain below.					
Explanation: Use additional page(s) if necessary. (For section I and Section II.) Notification of minor changes to the disclaimer statement per PR Notice 98-10. This notification is submitted in response to California Notice to Registrants 2004-3 which requires changes to the "Disclaimer" section of the label (See attached draft label for proposed changes). This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.							
Section - III							
1. Material This Product Will Be Packaged In:				2. Type of Container			
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
If "Yes" Unit Packaging wgt.		No. per container		If "Yes" Package wgt.		No. per container	
2. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container				4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled				<input type="checkbox"/> Other _____			
Section - IV							
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)*							
Name		Title		Telephone No. (Include Area Code)			
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment as both under applicable law.						6. Date Application Received (Stamp)	
2. Signature 		3. Title Senior Regulatory Affairs Specialist - Pharmaceuticals					
4. Typed Name Mary K. Hagler		5. Date 08 March 05					

NOTIFICATION
MAR 21 2005

Taktic®

EMULSIFIABLE CONCENTRATE
MITICIDE/INSECTICIDE

FOR THE CONTROL OF TICKS, MANGE MITES AND
LICE ON BEEF CATTLE, DAIRY CATTLE AND SWINE

DO NOT USE ON DOGS OR HORSES (MAY CAUSE FATAL COLON IMPACTION)

ACTIVE INGREDIENT:

Amitraz

INERT INGREDIENTS:

Percent by Weight:

12.5

87.5

TOTAL 100.0

This product contains Petroleum Distillate.

EPA Reg. No. 54382-3

U.S. Patent Nos. 3,781,355 and 3,864,497

EPA Est. No. 264-CAN-001

USUARIO: Si usted no lee inglés, no use este producto
hasta que la etiqueta haya sido explicada ampliamente.

(TO THE USER: If you cannot read English, do not use this
product until the label has been fully explained to you.)

KEEP OUT OF REACH OF CHILDREN

DANGER-PELIGRO

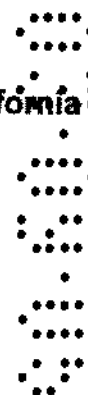
SEE BACK PANEL FOR ADDITIONAL PRECAUTIONARY
STATEMENTS

**NOTICE: This product contains a chemical known to the State of California
to cause birth defects or other reproductive harm.**

INTERVET INC.
Millsboro, DE 19966
584300D

Product of Canada

NET CONTENTS: 760 ml (25.7 fl. oz.)



FIRST AID:

IF SWALLOWED:	<ul style="list-style-type: none">• Immediately call a poison control center or doctor.• Do not induce vomiting unless told to do so by a poison control center or doctor.• Do not give any liquid to the person.• Do not give anything to an unconscious person.
IF IN EYES:	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.• Call a poison control center or doctor for treatment advice.
IF ON SKIN:	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice.
IF INHALED:	<ul style="list-style-type: none">• Move person to fresh air.• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.• Call a poison control center or doctor for further treatment advice.
For incidents involving HUMANS , call 1-800-228-5635, ext 132 For incidents involving ANIMALS , call 1-800-345-4735, ext 104 Have the product container or label with you when calling a poison control center or doctor or going for treatment	
NOTE TO PHYSICIAN: Amitraz, the active ingredient in this product, is a carbamate. Do not use atropine as an antidote. Treat any overexposure symptomatically. Mucosal damage is probable which increases the risk of gastric lavage. Contains petroleum distillate – vomiting may cause aspiration pneumonia.	

PRECAUTIONARY STATEMENTS

Hazards to Humans (and Domestic Animals)

DANGER

Corrosive. Causes irreversible eye damage. Causes skin irritation. Harmful if swallowed or absorbed through skin or inhaled. Do not get in eyes, on skin or on clothing. Avoid breathing spray mist. Wear goggles or face shield. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

Personal Protective Equipment (PPE)

Applicators and other handlers must wear:

- Chemical-resistant apron or coveralls over long-sleeved shirt and long pants.
- Chemical-resistant footwear plus socks.
- Chemical-resistant gloves.
- Chemical-resistant headgear for overhead exposure.
- Goggles or face shield, and chemical-resistant apron when cleaning equipment, mixing or loading.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.

For livestock spray or dip applications in enclosed areas: Apply only in well-ventilated areas.

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions exist for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

User Safety Recommendations

- Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish and aquatic invertebrates. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean water mark. Drift and runoff from treated areas may be hazardous to aquatic organisms in adjacent sites. Do not contaminate water when disposing of equipment washwaters or rinsate.

PHYSICAL OR CHEMICAL HAZARDS

Do not use or store near heat or open flame.

STORAGE AND DISPOSAL

STORAGE: Not for storage in and around the home environment. Store in original container in a locked dry place. Do not open the container until ready to use. Use entire contents of can when opened. Keep from freezing.

PESTICIDE DISPOSAL: Do not contaminate water, food or feed by storage or disposal. Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of federal law. If these wastes cannot be disposed of by use according to label instructions, contact your state pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

In case of spillage, cover with an absorbent such as soda ash, clay or sawdust. Sweep up and dispose of as directed under Storage and Disposal.

DO NOT REUSE EMPTY CONTAINER.

CHEMICAL EMERGENCY PHONE NUMBER (SPILL, LEAK, FIRE OR EXPOSURE)

1-800-424-9300

DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

DO NOT USE ON HORSES or DOGS ~ CAN CAUSE DEATHS.

DO NOT OPEN CONTAINER UNTIL READY TO USE.

USE TAKTIC® E.C. WITH WATER ONLY. DO NOT MIX WITH OIL OR OTHER SOLVENTS.



BEEF AND DAIRY CATTLE

TAKTIC® E.C. can be used on lactating dairy animals, with no withholding period for milk following application. Also, there is no post-treatment slaughter interval on beef and dairy cattle.

TICKS AND LICE:

TAKTIC® E.C. will control the following Ticks and Lice on cattle:

Lone Star Tick (*Amblyomma americanum*)

Gulf Coast Tick (*A. maculatum*)

Winter Tick (*Dermacentor albipictus*)

Brown Dog Tick (*Rhipicephalus sanguineus*)

American Dog Tick (*D. variabilis*)

Rocky Mountain Wood Tick (*D. andersoni*)

Spinose Ear Tick (*Otobius megnini*)

Black-legged Tick (*Ixodes scapularis*)

Tropical Bont Tick (*A. variegatum*)

Cayenne Tick (*A. cajennense*)

Cattle Tick (*Boophilus annulatus*)

Southern Cattle Tick (*B. microplus*)

Biting Louse (*Damalinia bovis*)

Sucking Lice (*Haematopinus eurysternus*, *Linognathus vituli*, *Solenopotes capillatus*)

MITES

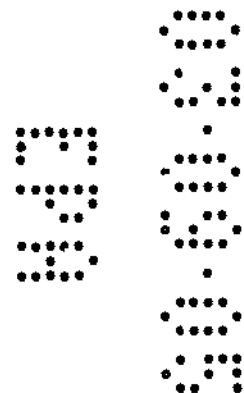
Scab and Mange Mites (*Chorioptes bovis*, *Psoroptes ovis* and *Sarcoptes scabiei* var. *bovis*)

Spray:

For control of ticks and lice, mix one can (760 ml) of TAKTIC® E.C. in 100 gallons of water; for control of mites, mix one can of TAKTIC® E.C. in 50 gallons of water. **Use TAKTIC® solutions within 6 hours of mixing.** Use up to 2 gallons of spray for a fully grown animal. It is important to wet the animal thoroughly and that the spray penetrates to the skin until run-off. For Lone Star ticks, cattle ticks, sucking lice and chewing lice, particular attention should be given to the legs, axilla and groin area, udder, tail regions and head, including the ears. For Gulf Coast ticks and Ear ticks, treat the head, ears, shoulder area and neck with a low pressure spray. For control of lice, a second treatment 10-14 days later is recommended, to kill lice hatching from eggs.

Spray Dip Machine:

For control of ticks and lice, mix one can (760 ml) of TAKTIC® E.C. in 100 gallons of water; for control of mites, mix one can of TAKTIC® E.C. in 50 gallons of water. To control cattle scabies, applications should be made as instructed by USDA, APHIS, VS bulletins. Two treatments 7-10 days apart are required to control cattle scabies. **Use TAKTIC® solutions within 6 hours of mixing.** Use up to 2 gallons of spray for a fully grown animal. It is important to wet the animal thoroughly and that the spray penetrates to the skin until run-off.



SWINE

MANGE MITE AND LOUSE (*Sarcoptes scabiei* var. *suis* and *Haematopinus suis*):

IMPORTANT

Remove feed from pen and cover drinking bowls. Remove and destroy bedding. Hose out feces and excess feed. Use TAKTIC® solutions within 6 hours of mixing.

Spray:

Mix one can (760 ml) TAKTIC® E.C. in 50 gallons of water (equivalent to 1/2 fl. ounce per gallon of spray solution). A sprayer with a coarse nozzle delivering the solution at 70 to 150 psi is recommended. Spray the walls, floor and any fittings in the pen. Spray all animals (at the same time) whether visibly affected or not. Spray the animals until the mixture runs off, paying particular attention to treat the jaw, legs, inside the ears and underside of the body. It is important that the spray penetrates to the skin until runoff. A second treatment is recommended to break the parasites' life cycles. Make the application 7-10 days after the first treatment for mite control, and 10-14 days for lice control.

An alternate to spraying young pigs (piglets/weaners) is to dip them in a suitable-sized container. Dip 30 animals and then replace dip wash. Use dip wash to treat premises.

Do not treat animals more than 4 times per year.

Do not apply to swine within three days of slaughter.

Do not use TAKTIC® E.C. at the same time with any other Amltraz-containing product.

IMPORTANT NOTICE: DISCLAIMER

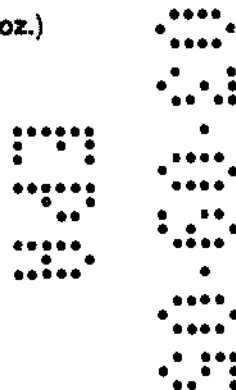
Read "IMPORTANT NOTICE: DISCLAIMER" before buying or using. If terms are not acceptable, return at once unopened. INTERVET warrants only that the product conforms to the chemical description on the label and is reasonably fit for the purpose stated on the label. ~~when used in accordance with the directions under normal conditions of use. This warranty does not extend to the use of this product contrary to label instructions or under abnormal conditions, or under conditions not reasonably foreseeable to INTERVET and user assumes the risk of any such use.~~ INTERVET MAKES NO OTHER WARRANTY, EXPRESSED OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE OR OF MERCHANTABILITY. In no case shall INTERVET be liable for consequential, special, indirect or incidental damages resulting from the use or handling of this product. The foregoing conditions of sale and warranty can be varied only by an agreement in writing signed by a duly authorized representative of INTERVET.

© 2002 INTERVET INC.

584350C

MADE IN CANADA

NET CONTENTS: 760 ml (25.7 fl. oz.)





(302) 934-4340

08 March 2005

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1801 South Bell Street
Arlington, VA 22202-4501

Dear EPA Notification Reviewer:

Please find enclosed a notification, per PR Notice 98-10, of minor label changes to the disclaimer statement for Taktic Emulsifiable Concentrate Miticide/Insecticide label (EPA Registration #: 54382-3; Intervet Inc., Company #: 54382). This notification is submitted in response to California Notice to Registrants 2004-3 which requires changes to the "Disclaimer" section of the label.

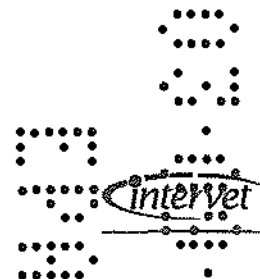
A completed EPA Form 8570-1 is enclosed as well as a copy of the proposed label. The proposed text to be removed is indicated by strikethrough and is also highlighted. In accordance with the PR notice, a stamped self-addressed envelope with note card identifying the notification and EPA Registration number is enclosed and we request confirmation of the acceptability of the proposed changes.

Thank you in advance for your attention to this matter. Please contact me by phone (302-934-4340) or e-mail (mary.hagler@Intervet.com) should you have any questions.

Sincerely,

Mary K. Hagler, MS
Senior Regulatory Affairs Specialist – Pharmaceuticals
Intervet Inc.

Enclosure



29160 Intervet
Lane

Intervet Inc.
405 State Street
P.O. Box 318
Millsboro, DE 19966-0318
Tel. (302) 934-8051
FAX (302) 934-6087



Please read instructions on reverse before completing form.

Form Approved, OMB No. 2070-0080, Approval expires 2-28-95



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 54382-3	2. EPA Product Manager Akiva Abramovitch	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Tactic Emulsifiable concentrate Miticide/insecticide	PM# 4	
5. Name and Address of Applicant (Include ZIP Code) Intervet Inc. 405 State St. Millsboro, DE 19966 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated <u>28 August 2002</u>
<input checked="" type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional pages if necessary. (For section I and Section II.)

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
If "Yes" Unit Packaging wgt. No. per container		If "Yes" Package wgt. No. per container			
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Mary K. Hagler		Title Regulatory Specialist - Pharmaceuticals		Telephone No. (Include Area Code) (302) 934-4340	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.				6. Date Application Received (Stamp)	
2. Signature <i>Mary K. Hagler</i>		3. Title Regulatory Specialist - Pharmaceuticals			
4. Typed Name Mary K. Hagler		5. Date 11 August 2003			

Taktic®

**EMULSIFIABLE CONCENTRATE
MITICIDE/INSECTICIDE**



FOR THE CONTROL OF TICKS, MANGE MITES AND
LICE ON BEEF CATTLE, DAIRY CATTLE AND SWINE

DO NOT USE ON OR WITH OTHER ANIMALS, CATTLE, CATTLE PRODUCTS

ACTIVE INGREDIENT	Percent by Weight
Artemez	12.5
INERT INGREDIENTS	87.5
	TOTAL 100.0

This product contains Petroleum Distillate

EPA Reg. No. 5000-2 (MCA) (MCA) (MCA) (MCA) (MCA) (MCA)
U.S. Patent Nos. 4,881,456 and 5,824,497

PRECAUTIONAL STATEMENT: Irritant to the eyes. See safety data sheet for
additional information regarding safe handling and use.

DO NOT USE on pregnant and lactating animals or their
product and/or milk may be toxic to offspring.

**KEEP OUT OF REACH OF CHILDREN
DANGER-PELIGRO**

SEE BACK PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

NOTICE: This product contains a chemical known to the State of California
to cause birth defects or other reproductive harm.

INTERVET INC.



Intervet
PRODUCT OF CANADA

NET CONTENTS: 750 ml (25.7 fl. oz.)

NOT REVIEWED
In Accordance with PR Notice 82-2
Based on Draft Labeling Dated

AUG 28 2003

IF SWALLOWED:	<ul style="list-style-type: none"> • Immediate • Do not induce vomiting unless told to do so by a poison control center or doctor. • Do not give any liquid to the person. • Do not give anything to an unconscious person.
IF IN EYES:	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. • Call a poison control center or doctor for treatment advice.
IF ON SKIN:	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
IF INHALED:	<ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. • Call a poison control center or doctor for further treatment advice.
<p>For incidents involving HUMANS, call 1-800-338-8335, ext 132 For incidents involving ANIMALS, call 1-800-245-4725, ext 154</p> <p>Have the product container or label with you when calling a poison control center or doctor or going for treatment.</p> <p>NOTE TO PHYSICIAN: Amitra, the active ingredient in this product, is a carbamate. Do not use terbufos as an antidote. Treat any overdosage symptomatically. Muscular damage is possible which increases the risk of gastric lavage. Contains paraoxon disulfate - vomiting may cause absorption precautions.</p>	

PULL HERE TO OPEN
PRESS TO RESEAL

PRECAUTIONARY STATEMENTS Hazards to Humans (and Domestic Animals)

DANGER

Corrosive. Causes irreversible eye damage. Causes skin irritation. Harmful if swallowed or absorbed through skin or inhaled. Do not get in eyes, on skin or on clothing. Avoid breathing spray mist. Wear goggles or face shield. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

Personal Protective Equipment (PPE)

- Applicators and other handlers must wear:
- Chemical-resistant apron or coveralls over long-sleeved shirt and long pants.
- Chemical-resistant footwear plus socks.
- Chemical-resistant gloves.
- Chemical-resistant headgear for overhead exposure.
- Goggles or face shield, and chemical-resistant apron when cleaning equipment, mixing or loading.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.

For livestock spray or dip applications in enclosed areas: Apply only in well-ventilated areas.

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions exist for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

User Safety Recommendations

- Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish and aquatic invertebrates. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean water mark. Drift and runoff from treated areas may be hazardous to aquatic organisms in adjacent sites. Do not contaminate water when disposing of equipment washwaters or rinsate.

PHYSICAL OR CHEMICAL HAZARDS

Do not use or store near heat or open flame.

STORAGE AND DISPOSAL

STORAGE: Not for storage in and around the home environment. Store in original container in a locked dry place. Do not open the container until ready to use. Use entire contents of can when opened. Keep from freezing.

PESTICIDE DISPOSAL: Do not contaminate water, food or feed by storage or disposal. Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of federal law. If these wastes cannot be disposed of by use according to label instructions, contact your state pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

In case of spillage, cover with an absorbent such as soda ash, clay or sawdust. Sweep up and dispose of as directed under Storage and Disposal.

DO NOT REUSE EMPTY CONTAINER.

CHEMICAL EMERGENCY PHONE NUMBER (SPILL, LEAK, FIRE OR EXPOSURE): 1-800-424-9300

DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

DO NOT USE ON HORSES OR DOGS - CAN CAUSE DEATHS.

DO NOT OPEN CONTAINER UNTIL READY TO USE.

USE TAKTIC® E.C. WITH WATER ONLY. DO NOT MIX WITH OIL OR OTHER SOLVENTS.

BEEF AND DAIRY CATTLE

TAKTIC® E.C. can be used on lactating dairy animals, with no withholding period for milk following application. Also, there is no post-treatment slaughter interval on beef and dairy cattle.

TICKS AND LICE:

TAKTIC® E.C. will control the following Ticks and Lice on cattle:

Lone Star Tick (*Amblyomma americanum*)
Gulf Coast Tick (*A. maculatum*)
Winter Tick (*Dermacentor albipictus*)
Brown Dog Tick (*Rhipicephalus sanguineus*)
American Dog Tick (*D. variabilis*)
Rocky Mountain Wood Tick (*D. andersoni*)
Spinose Ear Tick (*Otobius megnini*)
Black-legged Tick (*Ixodes scapularis*)
Tropical Bont Tick (*A. variegatum*)
Coyenne Tick (*A. caryanensis*)
Cattle Tick (*Boophilus annulatus*)
Southern Cattle Tick (*B. microplus*)
Biting Louse (*Haemaphysalis bovis*)
Sucking Lice (*Haematopinus eurysternus*, *Linognathus setosus*, *Solenopotes capillatus*)

MITE

Scab and Mange Mites (*Chorioptes bovis*, *Psoroptes ovis* and *Sarcoptes scabiei* var. *bovis*)

Spray:

For control of ticks and lice, mix one can (760 ml) of TAKTIC® E.C. in 100 gallons of water; for control of mites, mix one can of TAKTIC® E.C. in 50 gallons of water. **Use TAKTIC® solutions within 6 hours of mixing.** Use up to 2 gallons of spray for a fully grown animal. It is important to wet the animal thoroughly and that

the spray penetrates to the skin until run-off. For Lone Star ticks, cattle ticks, sucking lice and chewing lice, particular attention should be given to the legs, axilla and groin areas, udder, tail regions and head, including the ears. For Gulf Coast ticks and Ear ticks, treat the head, ears, shoulder area and neck with a low pressure spray. For control of lice, a second treatment 10-14 days later is recommended, to kill lice hatching from eggs.

Spray Dip Machine:

For control of ticks and lice, mix one can (760 ml) of TAKTIC® E.C. in 100 gallons of water; for control of mites, mix one can of TAKTIC® E.C. in 50 gallons of water. To control cattle scabies, applications should be made as instructed by USDA, APHIS, VS bulletins. Two treatments 7-10 days apart are required to control cattle scabies. **Use TAKTIC® solutions within 6 hours of mixing.** Use up to 2 gallons of spray for a fully grown animal. It is important to wet the animal thoroughly and that the spray penetrates to the skin until run-off.

SWINE

MANGE MITE AND LOUSE (*Sarcoptes scabiei* var. *swis* and *Haematopinus suis*):

IMPORTANT

Remove feed from pen and cover drinking bowls. Remove and destroy bedding. Hose out feces and excess feed. **Use TAKTIC® solutions within 6 hours of mixing.**

Spray:

Mix one can (760 ml) TAKTIC® E.C. in 50 gallons of water (equivalent to 1/2 fl. ounce per gallon of spray solution). A sprayer with a coarse nozzle delivering the solution at 70 to 150 psi is recommended. Spray the walls, floor and any fittings in the pen. Spray all animals (at the same time) whether visibly affected or not. Spray the animals until the mixture runs off, paying particular attention to treat the jaw, legs, inside the ears and underside of the body. It is important that the spray penetrates to the skin until run-off. A second treatment is recommended to break the parasites' life cycles. Make the application 7-10 days after the first treatment for mite control, and 10-14 days for lice control.

An alternate to spraying young pigs (piglets/weaners) is to dip them in a suitable-sized container. Dip 30 animals and then replace dip wash. Use dip wash to treat premises.

Do not treat animals more than 4 times per year.

Do not apply to swine within three days of slaughter.

Do not use TAKTIC® E.C. at the same time with any other Amitraz-containing product.

IMPORTANT NOTICE: DISCLAIMER

Read "IMPORTANT NOTICE: DISCLAIMER" before buying or using. If terms are not acceptable, return at once unopened. INTERVET warrants only that the product conforms to the chemical description on the label and is reasonably fit for the purposes stated on the label when used in accordance with the directions under normal conditions of use. This warranty does not extend to the use of this product contrary to label instructions or under abnormal conditions, or under conditions not reasonably foreseeable to INTERVET and user assumes the risk of any such use. INTERVET MAKES NO OTHER WARRANTY, EXPRESSED OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE OR OF MERCHANTABILITY. In no case shall INTERVET be liable for consequential, special, indirect or incidental damages resulting from the use or handling of this product. The foregoing conditions of sale and warranty can be varied only by an agreement in writing signed by a duly authorized representative of INTERVET.

© 2002 INTERVET INC.

5843506 MADE IN CANADA NET CONTENTS: 760 ml (25.7 fl. oz.)

**U.S. ENVIRONMENTAL PROTECTION AGENCY**

OFFICE OF PESTICIDE PROGRAMS

1200 Pennsylvania Ave., N.W.

Washington, DC 20460-0001

EPA Reg. Number

54382-3

Date of Issuance

AUG 28 2002

Term of Issuance

Unconditional

Name of Pesticide Product

TAKTIC EC

NOTICE OF PESTICIDE Registration X Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Intervet Inc.

405 State Street

P.O. Box 318

Millsboro, DE 19966

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby reregistered under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).

Registration is in no way to be construed as an endorsement or approval of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

Based on your response to the Amitraz Reregistration Eligibility Decision document, EPA has reregistered the product listed above. This action is taken under the authority of sec. 4(g)(2)(c) of FIFRA. Reregistration under this section does not eliminate the need for continued reassessment of pesticides. EPA may require submission of data any time to maintain the registration of your product.

The labeling submitted in connection with reregistration under the FIFRA is acceptable. A stamped copy of the draft label is enclosed for your records. Submit one (1) copy of your final printed labeling before you release the product for shipment. Should you have any questions, do not hesitate to contact Registration Review Manager, Dr. Akiva Abramovitch at 703-308-8328.

Signature of Approving Official:

Meredith Laws, Chief

Insecticide-Rodenticide Branch

Registration Division (7505C)

Date:

AUG 28 2002

**U.S. ENVIRONMENTAL PROTECTION AGENCY**

OFFICE OF PESTICIDE PROGRAMS

1200 Pennsylvania Ave., N.W.

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Signature of Approving Official:
Meredith Laws, Chief
Insecticide-Rodenticide Branch
Registration Division (7505C)

Date:

AUG 28 2002

Taktic®

EMULSIFIABLE CONCENTRATE
MITICIDE/INSECTICIDE

FOR THE CONTROL OF TICKS, MANGE MITES AND
LICE ON BEEF CATTLE, DAIRY CATTLE AND SWINE

DO NOT USE ON DOGS OR HORSES (MAY CAUSE FATAL COLON IMPACTION)

ACTIVE INGREDIENT:

Amitraz

INERT INGREDIENTS:

ACCEPTED

AUG 28 2002

Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide

Registered under
EPA Reg. No. 54382-3

Percent by Weight:

12.5

87.5

TOTAL 100.0

This product contains Petroleum

EPA Reg. No. 54382-3

U.S. Patent Nos. 3,781,355 and 3,864,497

EPA Est. No. 264-CAN-001

PRECAUCION AL USUARIO: Si usted no lee inglés, no use este producto
hasta que la etiqueta haya sido explicada ampliamente.

(TO THE USER: If you cannot read English, do not use this
product until the label has been fully explained to you.)

KEEP OUT OF REACH OF CHILDREN

DANGER-PELIGRO

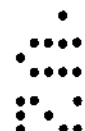
SEE BACK PANEL FOR ADDITIONAL PRECAUTIONARY
STATEMENTS

**NOTICE: This product contains a chemical known to the State of California
to cause birth defects or other reproductive harm.**

INTERVET INC.
Millsboro, DE 19966
584300C

Product of Canada

NET CONTENTS: 760 ml (25.7 fl. oz.)



FIRST AID:

IF SWALLOWED:	<ul style="list-style-type: none">• Immediately call a poison control center or doctor.• Do not induce vomiting unless told to do so by a poison control center or doctor.• Do not give any liquid to the person.• Do not give anything to an unconscious person.
IF IN EYES:	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.• Call a poison control center or doctor for treatment advice.
IF ON SKIN:	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice.
IF INHALED:	<ul style="list-style-type: none">• Move person to fresh air.• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.• Call a poison control center or doctor for further treatment advice.
For incidents involving HUMANS , call 1-800-228-5635, ext 132 For incidents involving ANIMALS , call 1-800-345-4735, ext 104 Have the product container or label with you when calling a poison control center or doctor or going for treatment	
NOTE TO PHYSICIAN: Amitraz, the active ingredient in this product, is a carbamate. Do not use atropine as an antidote. Treat any overexposure symptomatically. Mucosal damage is probable which increases the risk of gastric lavage. Contains petroleum distillate – vomiting may cause aspiration pneumonia.	

PRECAUTIONARY STATEMENTS

Hazards to Humans (and Domestic Animals)

DANGER

Corrosive. Causes irreversible eye damage. Causes skin irritation. Harmful if swallowed or absorbed through skin or inhaled. Do not get in eyes, on skin or on clothing. Avoid breathing spray mist. Wear goggles or face shield. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

Personal Protective Equipment (PPE)

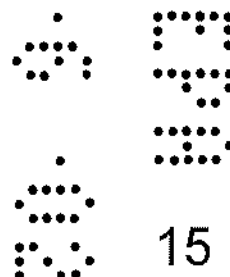
Applicators and other handlers must wear:

- Chemical-resistant apron or coveralls over long-sleeved shirt and long pants.
- Chemical-resistant footwear plus socks.
- Chemical-resistant gloves.
- Chemical-resistant headgear for overhead exposure.
- Goggles or face shield, and chemical-resistant apron when cleaning equipment, mixing or loading.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.

For livestock spray or dip applications in enclosed areas: Apply only in well-ventilated areas.

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions exist for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.



User Safety Recommendations

- Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish and aquatic invertebrates. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean water mark. Drift and runoff from treated areas may be hazardous to aquatic organisms in adjacent sites. Do not contaminate water when disposing of equipment washwaters or rinsate.

PHYSICAL OR CHEMICAL HAZARDS

Do not use or store near heat or open flame.

STORAGE AND DISPOSAL

STORAGE: Not for storage in and around the home environment. Store in original container in a locked dry place. Do not open the container until ready to use. Use entire contents of can when opened. Keep from freezing.

PESTICIDE DISPOSAL: Do not contaminate water, food or feed by storage or disposal. Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of federal law. If these wastes cannot be disposed of by use according to label instructions, contact your state pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

In case of spillage, cover with an absorbent such as soda ash, clay or sawdust. Sweep up and dispose of as directed under Storage and Disposal.

DO NOT REUSE EMPTY CONTAINER.

CHEMICAL EMERGENCY PHONE NUMBER (SPILL, LEAK, FIRE OR EXPOSURE)
1-800-424-9300

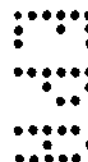
DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

DO NOT USE ON HORSES or DOGS -- CAN CAUSE DEATHS.

DO NOT OPEN CONTAINER UNTIL READY TO USE.

USE TAKTIC®E.C. WITH WATER ONLY. DO NOT MIX WITH OIL OR OTHER SOLVENTS.



BEEF AND DAIRY CATTLE

TAKTIC® E.C. can be used on lactating dairy animals, with no withholding period for milk following application. Also, there is no post-treatment slaughter interval on beef and dairy cattle.

TICKS AND LICE:

TAKTIC® E.C. will control the following Ticks and Lice on cattle:

Lone Star Tick (*Amblyomma americanum*)

Gulf Coast Tick (*A. maculatum*)

Winter Tick (*Dermacentor albipictus*)

Brown Dog Tick (*Rhipicephalus sanguineus*)

American Dog Tick (*D. variabilis*)

Rocky Mountain Wood Tick (*D. andersoni*)

Spinose Ear Tick (*Otobius megnini*)

Black-legged Tick (*Ixodes scapularis*)

Tropical Bont Tick (*A. variegatum*)

Cayenne Tick (*A. cajannense*)

Cattle Tick (*Boophilus annulatus*)

Southern Cattle Tick (*B. microplus*)

Biting Louse (*Damallinia bovis*)

Sucking Lice (*Haematopinus eurysternus*, *Linognathus vituli*, *Solenopotes capillatus*)

MITES

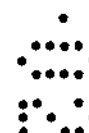
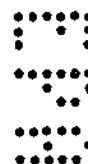
Scab and Mange Mites (*Chorioptes bovis*, *Psoroptes ovis* and *Sarcoptes scabiei* var. *bovis*)

Spray:

For control of ticks and lice, mix one can (760 ml) of TAKTIC® E.C. in 100 gallons of water; for control of mites, mix one can of TAKTIC® E.C. in 50 gallons of water. **Use TAKTIC® solutions within 6 hours of mixing.** Use up to 2 gallons of spray for a fully grown animal. It is important to wet the animal thoroughly and that the spray penetrates to the skin until run-off. For Lone Star ticks, cattle ticks, sucking lice and chewing lice, particular attention should be given to the legs, axilla and groin area, udder, tail regions and head, including the ears. For Gulf Coast ticks and Ear ticks, treat the head, ears, shoulder area and neck with a low pressure spray. For control of lice, a second treatment 10-14 days later is recommended, to kill lice hatching from eggs.

Spray Dip Machine:

For control of ticks and lice, mix one can (760 ml) of TAKTIC® E.C. in 100 gallons of water; for control of mites, mix one can of TAKTIC® E.C. in 50 gallons of water. To control cattle scabies, applications should be made as instructed by USDA, APHIS, VS bulletins. Two treatments 7-10 days apart are required to control cattle scabies. **Use TAKTIC® solutions within 6 hours of mixing.** Use up to 2 gallons of spray for a fully grown animal. It is important to wet the animal thoroughly and that the spray penetrates to the skin until run-off.



SWINE

MANGE MITE AND LOUSE (*Sarcoptes scabiei* var. *suis* and *Haematopinus suis*):

IMPORTANT

Remove feed from pen and cover drinking bowls. Remove and destroy bedding. Hose out feces and excess feed. Use TAKTIC® solutions within 6 hours of mixing.

Spray:

Mix one can (760 ml) TAKTIC® E.C. in 50 gallons of water (equivalent to 1/2 fl. ounce per gallon of spray solution). A sprayer with a coarse nozzle delivering the solution at 70 to 150 psi is recommended. Spray the walls, floor and any fittings in the pen. Spray all animals (at the same time) whether visibly affected or not. Spray the animals until the mixture runs off, paying particular attention to treat the jaw, legs, inside the ears and underside of the body. It is important that the spray penetrates to the skin until runoff. A second treatment is recommended to break the parasites' life cycles. Make the application 7-10 days after the first treatment for mite control, and 10-14 days for lice control.

An alternate to spraying young pigs (piglets/weaners) is to dip them in a suitable-sized container. Dip 30 animals and then replace dip wash. Use dip wash to treat premises.

Do not treat animals more than 4 times per year.

Do not apply to swine within three days of slaughter.

Do not use TAKTIC® E.C. at the same time with any other Amitraz-containing product.

IMPORTANT NOTICE: DISCLAIMER

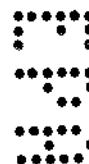
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© 2002 INTERVET INC.

584350B

MADE IN CANADA

NET CONTENTS: 760 ml (25.7 fl. oz.)





B

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 2-28-95



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number

294603

Application for Pesticide - Section I

1. Company/Product Number 54382-3	2. EPA Product Manager Akiva Abramovitch	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Taktic Emulsifiable concentrate Miticide/Insecticide	PM# 04	
5. Name and Address of Applicant (Include ZIP Code) Intervet Inc. 405 State St. Millsboro, DE 19966 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(iii), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

The purpose of this submission is to revise the first aid statements for the Taktic label as required by PR Notice 2001-1. In addition, the following statement is being added to the front label: "NOTICE: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm." (per California EPA's Proposition 65 requirements).

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
Certification must be submitted If "Yes" Unit Packaging wgt. No. per container		If "Yes" Package wgt. No. per container			
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other _____					

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Mary K. Hagler		Title Regulatory Specialist - Pharmaceuticals		Telephone No. (Include Area Code) (302) 934-4340	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature 		3. Title Regulatory Specialist - Pharmaceuticals			
4. Typed Name Mary K. Hagler		5. Date 02 May 2002			

Paperwork Reduction Act Notice and Instructions

Paperwork Reduction Act Notice: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, D.C. 20460.

Instructions: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

Specific Instructions: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

Section I - This section must be completed, as applicable, for all registration actions.

1. **Company/Product Number** - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager** - If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification** - Specify the proposed classification of this product.
4. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from the party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review** - FIFRA section 3(c) 3(b) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar, or identical to other pesticide products that are currently registered with the EPA. In order for you application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

Section II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. **Subject of submission** - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by . . ."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

Section III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Indicate the location of the net contents information for your product.
4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicate the method product label is attached to retail container.

Section IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

- 1-5. Self-explanatory
6. EPA Use only

A

B



(302) 934-4340

02 May 2002

Document Processing Desk (AMEND)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Attn: Akiva Abramovitch
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

**RE: Taktic Emulsifiable Concentrate Miticide/Insecticide
EPA Reg. No. 54382-3**

Dear Dr. Abramovitch,

In accordance with PR Notice 2001-1, enclosed is an amendment for the First Aid statements for the Taktic Emulsifiable Concentrate Miticide/Insecticide label (EPA Registration # 54382-3).

In addition, the following statement is being added to the front of the label as required by California EPA's Proposition 65: "NOTICE: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm."

A completed EPA Form 8570-1 is enclosed as well as a 5 copies of the draft label. The proposed changes to the label are highlighted in yellow on each of the 5 copies.

Thank you in advance for your attention to this matter. Please contact me by phone (302-934-4340) or e-mail (mary.hagler@intervet.com) should you have any questions.

Sincerely,

A handwritten signature in cursive script that reads "Mary K. Hagler".

Mary K. Hagler, MS
Regulatory Specialist – Pharmaceuticals
Intervet Inc.

Enclosure



Intervet Inc.
405 State Street
P.O. Box 318
Millsboro, DE 19966-0318
Tel. (302) 934-8051
FAX (302) 934-4292



**U.S. ENVIRONMENTAL PROTECTION AGENCY**

OFFICE OF PESTICIDE PROGRAMS

1200 Pennsylvania Ave., N.W.

Washington, DC 20460-0001

EPA Reg. Number

54382-3

Date of Issuance

AUG 28 2002

Term of Issuance

Unconditional

Name of Pesticide Product

TAKTIC EC

NOTICE OF PESTICIDE☐ Registration☒ Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

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Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby reregistered under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).

Registration is in no way to be construed as an endorsement or approval of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

Based on your response to the Amitraz Reregistration Eligibility Decision document, EPA has reregistered the product listed above. This action is taken under the authority of sec. 4(g)(2)(c) of FIFRA. Reregistration under this section does not eliminate the need for continued reassessment of pesticides. EPA may require submission of data any time to maintain the registration of your product.

The labeling submitted in connection with reregistration under the FIFRA is acceptable. A stamped copy of the draft label is enclosed for your records. Submit one (1) copy of your final printed labeling before you release the product for shipment. Should you have any questions, do not hesitate to contact Registration Review Manager, Dr. Akiva Abramovitch at 703-308-8328.

Signature of Approving Official:

Meredith Laws, Chief

Insecticide-Rodenticide Branch

Registration Division (7505C)

Date:

AUG 28 2002

Taktic®

EMULSIFIABLE CONCENTRATE MITICIDE/INSECTICIDE

FOR THE CONTROL OF TICKS, MANGE MITES AND
LICE ON BEEF CATTLE, DAIRY CATTLE AND SWINE

DO NOT USE ON DOGS OR HORSES (MAY CAUSE FATAL COLON IMPACTION)

ACTIVE INGREDIENT:

Amitrax

INERT INGREDIENTS:

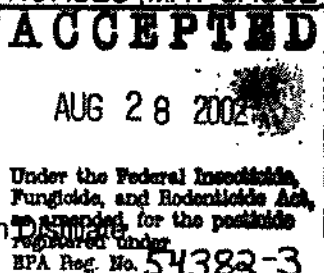
Percent by Weight:

12.5

87.5

TOTAL 100.0

This product contains Petroleum Distillate



EPA Reg. No. 54382-3

U.S. Patent Nos. 3,781,355 and 3,864,497

EPA Est. No. 264-CAN-001

PRECAUCION AL USUARIO: Si usted no lee inglés, no use este producto
hasta que la etiqueta haya sido explicada ampliamente.

(TO THE USER: If you cannot read English, do not use this
product until the label has been fully explained to you.)

KEEP OUT OF REACH OF CHILDREN

DANGER-PELIGRO

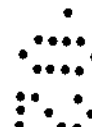
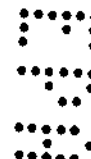
SEE BACK PANEL FOR ADDITIONAL PRECAUTIONARY
STATEMENTS

**NOTICE: This product contains a chemical known to the State of California
to cause birth defects or other reproductive harm.**

INTERVET INC.
Millsboro, DE 19966
584300C

Product of Canada

NET CONTENTS: 760 ml (25.7 fl. oz.)



FIRST AID:

IF SWALLOWED:	<ul style="list-style-type: none">• Immediately call a poison control center or doctor.• Do not induce vomiting unless told to do so by a poison control center or doctor.• Do not give any liquid to the person.• Do not give anything to an unconscious person.
IF IN EYES:	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.• Call a poison control center or doctor for treatment advice.
IF ON SKIN:	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice.
IF INHALED:	<ul style="list-style-type: none">• Move person to fresh air.• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.• Call a poison control center or doctor for further treatment advice.
For incidents involving HUMANS , call 1-800-228-5635, ext 132 For incidents involving ANIMALS , call 1-800-345-4735, ext 104 Have the product container or label with you when calling a poison control center or doctor or going for treatment	
NOTE TO PHYSICIAN: Amitraz, the active ingredient in this product, is a carbamate. Do not use atropine as an antidote. Treat any overexposure symptomatically. Mucosal damage is probable which increases the risk of gastric lavage. Contains petroleum distillate – vomiting may cause aspiration pneumonia.	

PRECAUTIONARY STATEMENTS

Hazards to Humans (and Domestic Animals)

DANGER

Corrosive. Causes irreversible eye damage. Causes skin irritation. Harmful if swallowed or absorbed through skin or inhaled. Do not get in eyes, on skin or on clothing. Avoid breathing spray mist. Wear goggles or face shield. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

Personal Protective Equipment (PPE)

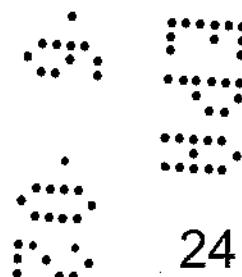
Applicators and other handlers must wear:

- Chemical-resistant apron or coveralls over long-sleeved shirt and long pants.
- Chemical-resistant footwear plus socks.
- Chemical-resistant gloves.
- Chemical-resistant headgear for overhead exposure.
- Goggles or face shield, and chemical-resistant apron when cleaning equipment, mixing or loading.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.

For livestock spray or dip applications in enclosed areas: Apply only in well-ventilated areas.

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions exist for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.



User Safety Recommendations

- Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish and aquatic invertebrates. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean water mark. Drift and runoff from treated areas may be hazardous to aquatic organisms in adjacent sites. Do not contaminate water when disposing of equipment washwaters or rinsate.

PHYSICAL OR CHEMICAL HAZARDS

Do not use or store near heat or open flame.

STORAGE AND DISPOSAL

STORAGE: Not for storage in and around the home environment. Store in original container in a locked dry place. Do not open the container until ready to use. Use entire contents of can when opened. Keep from freezing.

PESTICIDE DISPOSAL: Do not contaminate water, food or feed by storage or disposal. Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of federal law. If these wastes cannot be disposed of by use according to label instructions, contact your state pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

In case of spillage, cover with an absorbent such as soda ash, clay or sawdust. Sweep up and dispose of as directed under Storage and Disposal.

DO NOT REUSE EMPTY CONTAINER.

CHEMICAL EMERGENCY PHONE NUMBER (SPILL, LEAK, FIRE OR EXPOSURE)

1-800-424-9300

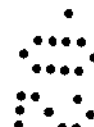
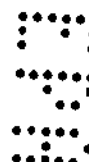
DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

DO NOT USE ON HORSES or DOGS – CAN CAUSE DEATHS.

DO NOT OPEN CONTAINER UNTIL READY TO USE.

USE TAKTIC®E.C. WITH WATER ONLY. DO NOT MIX WITH OIL OR OTHER SOLVENTS.



BEEF AND DAIRY CATTLE

TAKTIC® E.C. can be used on lactating dairy animals, with no withholding period for milk following application. Also, there is no post-treatment slaughter interval on beef and dairy cattle.

TICKS AND LICE:

TAKTIC® E.C. will control the following Ticks and Lice on cattle:

Lone Star Tick (*Amblyomma americanum*)

Gulf Coast Tick (*A. maculatum*)

Winter Tick (*Dermacentor albipictus*)

Brown Dog Tick (*Rhipicephalus sanguineus*)

American Dog Tick (*D. variabilis*)

Rocky Mountain Wood Tick (*D. andersoni*)

Spinose Ear Tick (*Otobius megnini*)

Black-legged Tick (*Ixodes scapularis*)

Tropical Bont Tick (*A. variegatum*)

Cayenne Tick (*A. cajennense*)

Cattle Tick (*Boophilus annulatus*)

Southern Cattle Tick (*B. microplus*)

Biting Louse (*Damalinia bovis*)

Sucking Lice (*Haematopinus eurysternus*, *Linognathus vituli*, *Solenopotes capillatus*)

MITES

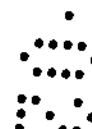
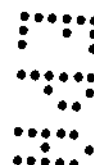
Scab and Mange Mites (*Chorioptes bovis*, *Psoroptes ovis* and *Sarcoptes scabiei* var. *bovis*)

Spray:

For control of ticks and lice, mix one can (760 ml) of TAKTIC® E.C. in 100 gallons of water; for control of mites, mix one can of TAKTIC® E.C. in 50 gallons of water. **Use TAKTIC® solutions within 6 hours of mixing.** Use up to 2 gallons of spray for a fully grown animal. It is important to wet the animal thoroughly and that the spray penetrates to the skin until run-off. For Lone Star ticks, cattle ticks, sucking lice and chewing lice, particular attention should be given to the legs, axilla and groin area, udder, tail regions and head, including the ears. For Gulf Coast ticks and Ear ticks, treat the head, ears, shoulder area and neck with a low pressure spray. For control of lice, a second treatment 10-14 days later is recommended, to kill lice hatching from eggs.

Spray Dip Machine:

For control of ticks and lice, mix one can (760 ml) of TAKTIC® E.C. in 100 gallons of water; for control of mites, mix one can of TAKTIC® E.C. in 50 gallons of water. To control cattle scabies, applications should be made as instructed by USDA, APHIS, VS bulletins. Two treatments 7-10 days apart are required to control cattle scabies. **Use TAKTIC® solutions within 6 hours of mixing.** Use up to 2 gallons of spray for a fully grown animal. It is important to wet the animal thoroughly and that the spray penetrates to the skin until run-off.



SWINE

MANGE MITE AND LOUSE (*Sarcoptes scabiei* var. *suis* and *Haematopinus suis*):

IMPORTANT

Remove feed from pen and cover drinking bowls. Remove and destroy bedding. Hose out feces and excess feed. Use TAKTIC® solutions within 6 hours of mixing.

Spray:

Mix one can (760 ml) TAKTIC® E.C. in 50 gallons of water (equivalent to 1/2 fl. ounce per gallon of spray solution). A sprayer with a coarse nozzle delivering the solution at 70 to 150 psi is recommended. Spray the walls, floor and any fittings in the pen. Spray all animals (at the same time) whether visibly affected or not. Spray the animals until the mixture runs off, paying particular attention to treat the jaw, legs, inside the ears and underside of the body. It is important that the spray penetrates to the skin until runoff. A second treatment is recommended to break the parasites' life cycles. Make the application 7-10 days after the first treatment for mite control, and 10-14 days for lice control.

An alternate to spraying young pigs (piglets/weaners) is to dip them in a suitable-sized container. Dip 30 animals and then replace dip wash. Use dip wash to treat premises.

Do not treat animals more than 4 times per year.

Do not apply to swine within three days of slaughter.

Do not use TAKTIC® E.C. at the same time with any other Amitraz-containing product.

IMPORTANT NOTICE: DISCLAIMER

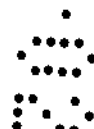
Read "IMPORTANT NOTICE: DISCLAIMER" before buying or using. If terms are not acceptable, return at once unopened. INTERVET warrants only that the product conforms to the chemical description on the label and is reasonably fit for the purpose stated on the label when used in accordance with the directions under normal conditions of use. This warranty does not extend to the use of this product contrary to label instructions or under abnormal conditions, or under conditions not reasonably foreseeable to INTERVET and user assumes the risk of any such use. INTERVET MAKES NO OTHER WARRANTY, EXPRESSED OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE OR OF MERCHANTABILITY. In no case shall INTERVET be liable for consequential, special, indirect or incidental damages resulting from the use or handling of this product. The foregoing conditions of sale and warranty can be varied only by an agreement in writing signed by a duly authorized representative of INTERVET.

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584350B

MADE IN CANADA

NET CONTENTS: 760 ml (25.7 fl. oz.)



Taktic®

EMULSIFIABLE CONCENTRATE
MITICIDE/INSECTICIDE



FOR THE CONTROL OF TICKS, RANGE MITES AND
LICE ON BEEF CATTLE, DAIRY CATTLE AND SWINE

©1994 Intervet Inc. All rights reserved. Intervet Inc. is a registered trademark of Intervet Inc.

ACTIVE INGREDIENT	Permethrin (Technical)
Adjuvant	12.5
INERT INGREDIENTS	87.5
	TOTAL 100.0

This product contains Permethrin (Technical)

EPA Reg. No. 34107-3 EPA Est. No. 764-CA-001
U.S. Patent Nos. 3,781, 074 and 3,884, 917

DIRECTIONS FOR USE: See label for directions. Do not use this
product on horses or dogs. Do not use on pregnant animals.

(TO THE USER: If you are using this product, do not use this
product on horses or dogs. Do not use on pregnant animals.)

KEEP OUT OF REACH OF CHILDREN

ANGER-PELIGRO

SEE STATEMENT OF PRACTICAL
TREATMENT ON REAR LABEL PANEL

INTERVET INC.
Millsboro, DE 19966
(302) 398-1000


Product of Canada

NET CONTENTS: 760 ml (25.7 fl. oz.)

843

10-02-00

STATEMENT OF PRACTICAL TREATMENT (FIRST AID):

IF IN EYES: HOLD EYELIDS OPEN AND FLUSH WITH STEADY, GENTLE STREAM OF WATER FOR 15 MINUTES. GET MEDICAL ATTENTION.
IF ON SKIN: WASH WITH PLenty OF SOAP AND WATER. GET MEDICAL ATTENTION.
IF INHALED: REMOVE VICTIM TO FRESH AIR. IF NOT BREATHING, GIVE ARTIFICIAL RESPIRATION, PREFERABLY MOUTH-TO-MOUTH. GET MEDICAL ATTENTION.
IF SWALLOWED: CALL A PHYSICIAN OR POISON CONTROL CENTER. DO NOT INDUCE VOMITING. DRINK PROMPTLY A LARGE QUANTITY OF MILK, EGG WHITES, GELATIN SOLUTION, OR IF THESE ARE NOT AVAILABLE, DRINK LARGE QUANTITIES OF WATER. AVOID ALCOHOL.

NOTE TO PHYSICIAN: AMITRAZ, THE ACTIVE INGREDIENT IN THIS PRODUCT, IS NOT AN ORGANOPHOSPHORUS COMPOUND. DO NOT USE ATROPINE AS AN ANTIDOTE. TREAT ANY OVEREXPOSURE SYMPTOMATICALLY. MUCCOSAL DAMAGE IS PROBABLE WHICH INCREASES THE RISK OF GASTRIC LAVAGE. THE PRESENCE OF PETROLIUM DISTILLATE IN THIS PRODUCT MAY POSE AN ASPIRATION PNEUMONIA HAZARD.

PRECAUTIONARY STATEMENTS Hazards to Humans (and Domestic Animals)

DANGER

Corrosive. Causes irreversible eye damage. Causes skin irritation. Harmful if swallowed or absorbed through skin or inhaled. Do not get in eyes, on skin or on clothing. Avoid breathing spray mist. Wear goggles or face shield. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

Personal Protective Equipment (PPE)

Applicators and other handlers must wear:

- Chemical-resistant apron or coveralls over long-sleeved shirt and long pants.
- Chemical-resistant footwear plus socks.
- Chemical-resistant gloves.
- Chemical-resistant headgear for overhead exposure.
- Goggles or face shield, and chemical-resistant apron when cleaning equipment, mixing or loading.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.

For livestock spray or dip applications in enclosed areas: Apply only in well-ventilated areas.

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions exist for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

User Safety Recommendations

- Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish and aquatic invertebrates. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean water mark. Drift and runoff from treated areas may be hazardous to aquatic organisms in adjacent areas. Do not contaminate water when disposing of equipment washwaters or rinsate.

PHYSICAL OR CHEMICAL HAZARDS

Do not use or store near heat or open flame.

STORAGE AND DISPOSAL

STORAGE: Not for storage in and around the home environment. Store in original container in a locked dry place. Do not open the container until ready to use. Use entire contents of can when opened. Keep from freezing.

PULL HERE TO OPEN
PRESS TO RESEAL

043

10-00-00

PESTICIDE DISPOSAL: Do not contaminate water, food or feed by storage or disposal. Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture or residue is a violation of federal law. If these wastes cannot be disposed of by use according to label instructions, contact your state pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

In case of spillage, cover with an absorbent such as soda ash, clay or sawdust. Sweep up and dispose of as directed under Storage and Disposal.

DO NOT REUSE EMPTY CONTAINER.

EMERGENCY PHONE NOS.:

HUMAN — 1-800-238-8836, ext. 132

ANIMAL — 1-800-345-4735, ext. 104

CHEMICAL (SPILL, LEAK, FIRE OR EXPOSURE) 1-800-424-9300

DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

DO NOT USE ON HORSES or DOGS - CAN CAUSE DEATHS.

DO NOT OPEN CONTAINER UNTIL READY TO USE.

USE TAKTIC® E.C. WITH WATER ONLY. DO NOT MIX WITH OIL OR OTHER SOLVENTS.

BEEF AND DAIRY CATTLE

TAKTIC® E.C. can be used on lactating dairy animals, with no withholding period for milk following application. Also, there is no post-treatment slaughter interval on beef and dairy cattle.

TICKS AND LICE

TAKTIC® E.C. will control the following Ticks and Lice on cattle:

Lone Star Tick (*Amblyomma americanum*)

Gulf Coast Tick (*A. maculatum*)

Winter Tick (*Dermacentor albipictus*)

Brown Dog Tick (*Rhipicephalus sanguineus*)

American Dog Tick (*D. variabilis*)

Rocky Mountain Wood Tick (*D. andersoni*)

Spinose Ear Tick (*Otobius megnini*)

Black-legged Tick (*Ixodes scapularis*)

Tropical Bont Tick (*A. variegatum*)

Cayenne Tick (*A. cajennense*)

Cattle Tick (*Bosophilus annulatus*)

Southern Cattle Tick (*B. microplus*)

Biting Lice (*Haematopinus asinus*)

Sucking Lice (*Haematopinus eurysternus*, *Linognathus setosus*, *Solenopotes capillatus*)

MITE

Scab and Mange Mites (*Chorioptes bovis*, *Psaroptes ovis* and *Sarcoptes scabiei* var. *bovis*)

Spray:

For control of ticks and lice, mix one can (760 ml) of TAKTIC® E.C. in 100 gallons of water; for control of mites, mix one can of TAKTIC® E.C. in 50 gallons of water. Use TAKTIC® solutions within 8 hours of mixing. Use up to 2 gallons of spray for a fully grown animal. It is important to wet the animal thoroughly and that the spray penetrates to the skin until run-off. For Lone Star ticks, cattle ticks, sucking lice and chewing lice, particular attention

should be given to the legs, axilla and groin area, udder, tail region and head, including the ears. For Gulf Coast ticks and Ear ticks, treat the head, ears, shoulder area and neck with a low pressure spray. For control of lice, a second treatment 10-14 days later is recommended, to kill lice hatching from eggs.

Spray Dip Machine:

For control of ticks and lice, mix one can (760 ml) of TAKTIC® E.C. in 100 gallons of water; for control of mites, mix one can of TAKTIC® E.C. in 50 gallons of water. To control cattle scabies, applications should be made as instructed by USDA, APHIS, VS Bulletin. Two treatments 7-10 days apart are required to control cattle scabies. Use TAKTIC® solutions within 8 hours of mixing. Use up to 2 gallons of spray for a fully grown animal. It is important to wet the animal thoroughly and that the spray penetrates to the skin until run-off.

SWINE

MANGE MITE AND LOUSE (*Sarcoptes scabiei* var. *swine* and *Haematopinus suis*):

IMPORTANT

Remove feed from pen and cover drinking bowls. Remove and destroy bedding. Hoss out feces and excess feed. Use TAKTIC® solutions within 8 hours of mixing.

Spray:

Mix one can (760 ml) TAKTIC® E.C. in 50 gallons of water (equivalent to 1/2 fl. ounce per gallon of spray solution). A sprayer with a coarse nozzle delivering the solution at 70 to 150 psi is recommended. Spray the walls, floor and any fittings in the pen. Spray all animals (at the same time) whether visibly affected or not. Spray the animals until the mixture runs off, paying particular attention to treat the jaw, legs, inside the ears and underside of the body. It is important that the spray penetrates to the skin until run-off. A second treatment is recommended to break the parasite's life cycle. Make the application 7-10 days after the first treatment for mite control, and 10-14 days for lice control.

An alternate to spraying young pigs (piglets/eweans) is to dip them in a suitable-sized container. Dip 30 animals and then replace dip wash. Use dip wash to treat premises.

Do not treat animals more than 4 times per year.

Do not apply to swine within three days of slaughter.

Do not use TAKTIC® E.C. at the same time with any other Anthelmintic-containing product.

IMPORTANT NOTICE: DISCLAIMER

Read "IMPORTANT NOTICE: DISCLAIMER" before buying or using. If there are no exceptions, return it once unopened. INTERVET warrants only that the product conforms to the chemical description on the label and is reasonably fit for the purposes stated on the label when used in accordance with the directions under normal conditions of use. This warranty does not extend to the use of this product contrary to label instructions or under abnormal conditions, or under conditions not reasonably foreseeable to INTERVET and user assumes the risk of any such use. INTERVET MAKES NO OTHER WARRANTY, EXPRESSED OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE OR MERCHANTABILITY. In no case shall INTERVET be liable for consequential, special, indirect or incidental damages resulting from the use or handling of this product. The foregoing conditions of sale and warranty can be varied only by an agreement in writing signed by a duly authorized representative of INTERVET.

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024262A MADE IN CANADA NET CONTENTS: 760 ml (25.3 fl. oz.)

043
10-02-00

Current Product Label

Taktic®

EMULSIFIABLE CONCENTRATE MITICIDE/INSECTICIDE



FOR THE CONTROL OF TICKS, MANGE MITES AND
LICE ON BEEF CATTLE, DAIRY CATTLE AND SWINE

Keep out of reach of children. See back of container for complete directions.

ACTIVE INGREDIENT	Percent by Weight
Ambroz	12.5
INERT INGREDIENTS	87.5
	TOTAL 100.0

This product contains Petroleum Distillate


EPA Reg. No. 1110-3 EPA Est. No. 764 CAN 001
USE: Diluted Mix. 1:400 (0.25%) and 1:800 (0.125%)

PRECAUTIONAL STATEMENT: See statement on page 2 of the product label.
Read the entire label carefully before using this product.

Do not use if you do not read English. Do not use if a
 printed word on the label has been fully imprinted in your

KEEP OUT OF REACH OF CHILDREN
ANGER-PELIGRO
SEE STATEMENT OF PRACTICAL
 TREATMENT ON NEXT LABEL PANEL

INTERVEL INC.
 2700 ...
 ...



Product of Canada

NET CONTENTS: 760 ml (25.7 fl. oz.)

843

10-02-00

PESTICIDE DISPOSAL: Do not contaminate water, food or feed by storage or disposal. Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture or residue is a violation of federal law. If these wastes cannot be disposed of by use according to label instructions, contact your state pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

In case of spillage, cover with an absorbent such as soda ash, clay or sawdust. Sweep up and dispose of as directed under Storage and Disposal.

DO NOT REUSE EMPTY CONTAINER.

EMERGENCY PHONE NOS.:

HUMAN — 1-800-228-6835, ext. 132

ANIMAL — 1-800-345-4735, ext. 104

CHEMICAL (SPILL, LEAK, FIRE OR EXPOSURE) 1-800-424-9300

DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

DO NOT USE ON HORSES OR DOGS — CAN CAUSE DEATHS.

DO NOT OPEN CONTAINER UNTIL READY TO USE.

USE TAKTIC® E.C. WITH WATER ONLY. DO NOT MIX WITH OIL OR OTHER SOLVENTS.

BEEF AND DAIRY CATTLE

TAKTIC® E.C. can be used on lactating dairy animals, with no withholding period for milk following application. Also, there is no post-treatment slaughter interval on beef and dairy cattle.

TICKS AND LICE:

TAKTIC® E.C. will control the following Ticks and Lice on cattle:

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American Dog Tick (*D. variabilis*)

Rocky Mountain Wood Tick (*D. andersoni*)

Spinose Ear Tick (*Otobius megnini*)

Black-legged Tick (*Ixodes scapularis*)

Tropical Bont Tick (*A. variegatum*)

Cayenne Tick (*A. cajennense*)

Cattle Tick (*Bovicapitus annulatus*)

Southern Cattle Tick (*B. microptus*)

Biting Lice (*Haematopinus asinus*)

Sucking Lice (*Haematopinus eurysternus*, *Linognathus vituli*, *Solanopotes capillatus*)

MITES

Scab and Mange Mites (*Chorioptes bovis*, *Pseudoscorpion* *scabiei* var. *bovis*)

Spray:

For control of ticks and lice, mix one can (760 ml) of TAKTIC® E.C. in 100 gallons of water; for control of mites, mix one can of TAKTIC® E.C. in 50 gallons of water. **Use TAKTIC® solutions within 6 hours of mixing.** Use up to 2 gallons of spray for a fully grown animal. It is important to wet the animal thoroughly and that the spray penetrates to the skin until run-off. For Lone Star ticks, cattle ticks, sucking lice and chewing lice, particular attention

should be given to the legs, axilla and groin area, udder, tail regions and head, including the ears. For Gulf Coast ticks and Ear ticks, treat the head, ears, shoulder area and neck with a low pressure spray. For control of lice, a second treatment 10-14 days later is recommended, to kill lice hatching from eggs.

Spray Dip Machine:

For control of ticks and lice, mix one can (760 ml) of TAKTIC® E.C. in 100 gallons of water; for control of mites, mix one can of TAKTIC® E.C. in 50 gallons of water. To control cattle scabies, applications should be made as instructed by USDA, APHIS, VS bulletins. Two treatments 7-10 days apart are required to control cattle scabies. **Use TAKTIC® solutions within 6 hours of mixing.** Use up to 2 gallons of spray for a fully grown animal. It is important to wet the animal thoroughly and that the spray penetrates to the skin until run-off.

SWINE

MANGE MITE AND LOUSE (*Sarcoptes scabiei* var. *swine* and *Haematopinus suis*):

IMPORTANT

Remove feed from pen and cover drinking bowls. Remove and destroy bedding. Isolate out feces and excess feed. **Use TAKTIC® solutions within 6 hours of mixing.**

Spray:

Mix one can (760 ml) TAKTIC® E.C. in 50 gallons of water (equivalent to 1/2 fl. ounce per gallon of spray solution). A sprayer with a coarse nozzle delivering the solution at 70 to 150 psi is recommended. Spray the walls, floor and any fittings in the pen. Spray all animals (at the same time) whether visibly affected or not. Spray the animals until the mixture runs off, paying particular attention to treat the joint, legs, inside the ears and underside of the body. It is important that the spray penetrates to the skin until run-off. A second treatment is recommended to break the parasites' life cycles. Make the application 7-10 days after the first treatment for mite control, and 10-14 days for lice control.

An alternate to spraying young pigs (piglets/weaners) is to dip them in a suitable-sized container. Dip 30 animals and then replace dip wash. Use dip wash to treat premises.

Do not treat animals more than 4 times per year.

Do not apply to swine within three days of slaughter.

Do not use TAKTIC® E.C. at the same time with any other Antimicrobial-containing product.

IMPORTANT NOTICE: DISCLAIMER

Read "IMPORTANT NOTICE: DISCLAIMER" before buying or using. If some are not acceptable, return at once unopened. INTERVET warrants only that the product conforms to the chemical description on the label and is reasonably fit for the purpose stated on the label when used in accordance with the directions under normal conditions of use. This warranty does not extend to the use of this product contrary to label instructions or under abnormal conditions, or under conditions not reasonably foreseeable to INTERVET and user assumes the risk of any such use. INTERVET MAKES NO OTHER WARRANTY, EXPRESSED OR IMPLIED INCLUDING ANY IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE OR OF MERCHANTABILITY. In no case shall INTERVET be liable for consequential, special, indirect or incidental damages resulting from the use or handling of this product. This foregoing warranty of sale and liability can be varied only by an agreement in writing signed by a duly authorized representative of INTERVET.

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584355A

MADE IN CANADA

NET CONTENTS: 750 ml (25.4 fl. oz.)

09-30-01

09-30-01



September 12, 2001

Akiva Abramovitch, Ph.D., Chemist
Insecticide-Rodenticide Branch
Registration Division (7505C)
USEPA Headquarters
Ariel Rios Building
1200 Pennsylvania Ave. N.W.
Washington, DC 20460

RE: Taktic[®] EC (amitraz); EPA Reg. No. 54382-3

Dear Dr. Abramovitch,

As requested in your phone message today, please find enclosed a current product label and a paper copy of the current product label for Taktic[®] EC. Also enclosed is a copy of the EPA stamped label (27 April 1999) that was faxed to you 07 September 2001.

Updated labels regarding PR Notice 2001-1 (First Aid Statements on Pesticide Product Labels) will be submitted at a later date.

If you have any further questions, please contact me by e-mail (lee.whaley@intervet.com) or by phone at (302) 934-4385.

Sincerely,

S. Lee Whaley, MS
Manager, Regulatory Affairs-Pharmaceuticals
Intervet Inc.

Enclosures

003

10.02.00



Intervet Inc.
405 State Street
P.O. Box 318
Millsboro, DE 19966 0318
Tel. (302) 934-8051
FAX (302) 934-4292

Label C — Proposed Label
January 11, 1999, 4 pages

ACCEPTED

APR 27 1999

Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, the pesticide
registered under
EPA Reg. No. 54382-3



This product contains Petroleum Distillate. →

Taktic®

**EMULSIFIABLE CONCENTRATE
MITICIDE/INSECTICIDE**



**FOR THE CONTROL OF TICKS, MANGE MITES AND
LICE ON BEEF CATTLE, DAIRY CATTLE AND SWINE**

DO NOT USE ON DOGS OR HORSES (MAY CAUSE FATAL COLIC/IMPACTIC)

ACTIVE INGREDIENT:	Percent by Weight
Amitraz	12.5
INERT INGREDIENTS	87.5
	TOTAL 100.0

This product contains a, long range repellent

EPA Reg. No. 54382-3

EPA Est. No. C45639-CAN-031

U.S. Patent Nos. 3,781,355 and 3,864,497

PRECAUCION AL USUARIO Si usted no lee inglés, no use este producto
hasta que la etiqueta haya sido explicado ampliamente

(TO THE USER: If you cannot read English, do not use this
product until the label has been fully explained to you.)

KEEP OUT OF REACH OF CHILDREN

DANGER-PELIGRO

SEE STATEMENT OF PRACTICAL
TREATMENT ON BACK LABEL

Hoechst Roussel Vet
3000 Parkway Blvd.
Parsippany, NJ 07054
(908) 261-1100

Hoechst
AG

Hoechst Roussel Vet is a registered trademark of Hoechst Roussel Vet GmbH.
The name and logo HOECHST are registered trademarks of Hoechst AG.

NET CONTENTS: 760 ml (25.7 fl. oz.)

STATEMENT OF PRACTICAL TREATMENT (FIRST AID):

(B) →

CONTROL CENTER IMMEDIATELY. IT IS PREFERRED TO USE GASTRIC LAVAGE UNDER MEDICAL SUPERVISION DUE TO ASPIRATION HAZARD. DO NOT INDUCE VOMITING OR GIVE ANYTHING BY MOUTH TO AN UNCONSCIOUS PERSON. MALAZ IS NOT AN ORGANOPHOSPHORUS COMPOUND. DO NOT USE ATROPINE AS AN ANTIDOTE.
IF IN EYES: FLUSH WITH PLENTY OF WATER. GET MEDICAL ATTENTION.
IF ON SKIN: WASH WITH SOAP AND WATER. REMOVE CONTAMINATED CLOTHING.

PRECAUTIONARY STATEMENTS Hazards to Humans (and Domestic Animals)

DANGER

(C) →

absorbed through skin. Repeated skin contact may cause an allergic reaction in certain individuals.

Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

Personal Protective Equipment (PPE)

Applicators and other handlers must wear:

Chemical-resistant apron over long-sleeved shirt and long pants.
Chemical-resistant footwear plus socks.
Chemical-resistant gloves.

Chemical-resistant headgear for overhead exposure.

Goggles or face shield, and chemical-resistant apron when cleaning equipment, mixing or loading.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.

For livestock spray or dip applications in enclosed areas: Apply only in well-ventilated areas.

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions exist for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

User Safety Recommendations

- Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish and aquatic invertebrates. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean water mark. Drift and runoff from treated areas may be hazardous to aquatic organisms in adjacent sites. Do not contaminate water when disposing of equipment washwaters or rinsate.

PHYSICAL OR CHEMICAL HAZARDS

Do not use or store near heat or open flame.

STORAGE AND DISPOSAL

STORAGE: Not for storage in and around the home environment. Store in original container in a locked, dry place. Do not open the container until ready to use. Use entire contents of can when opened. Keep from freezing.

IF IN EYES: Hold eyelids open and flush with steady, gentle stream of water for 15 minutes. Get medical attention.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention.

IF INHALED: Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical attention.

IF SWALLOWED: Call a physician or Poison Control Center. Do not induce vomiting. Drink promptly a large quantity of milk, egg whites, gelatin solution, or if these are not available, drink large quantities of water. Avoid alcohol.

NOTE TO PHYSICIAN:

Amitraz, the active ingredient in this product, is not an organophosphorus compound. Do not use atropine as an antidote. Treat any overexposure symptomatically. Mucosal damage is probable which increases the risk of gastric lavage. The presence of petroleum distillate in this product may pose an aspiration pneumonia hazard.

Corrosive. Causes irreversible eye damage. Causes skin irritation. Harmful if swallowed or absorbed through skin or inhaled. Do not get in eyes, on skin or on clothing. Avoid breathing spray mist. Wear goggles or face shield. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

PESTICIDE DISPOSAL: Do not contaminate water, food or feed by storage or disposal. Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of federal law. If these wastes cannot be disposed of by use according to label instructions, contact your state pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

In case of spillage, cover with an absorbent such as soda ash, clay or sawdust. Sweep up and dispose of as directed under Storage and Disposal.

DO NOT REUSE EMPTY CONTAINER.

EMERGENCY PHONE NOS.:

HUMAN, FIRE, SPILLS, ENVIRONMENTAL:
1-800-228-5835, Ext. 132

ANIMALS: 1-800-345-4735, Ext. 104

DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

DO NOT USE ON HORSES or DOGS - CAN CAUSE DEATHS.

DO NOT OPEN CONTAINER UNTIL READY TO USE.

USE TAKTIC® E.C. WITH WATER ONLY. DO NOT MIX WITH OIL OR OTHER SOLVENTS.

BEEF AND DAIRY CATTLE

TAKTIC® E.C. can be used on lactating dairy animals, with no withholding period for milk following application. Also, there is no post-treatment slaughter interval on beef and dairy cattle.

TICKS AND LICE:

TAKTIC® E.C. will control the following Ticks and Lice on cattle:

Lone Star Tick (*Amblyomma americanum*)

Gulf Coast Tick (*A. maculatum*)

Winter Tick (*Dermacentor albipictus*)

Brown Dog Tick (*Rhipicephalus sanguineus*)

American Dog Tick (*D. variabilis*)

Rocky Mountain Wood Tick (*Dermacentor andersoni*)

Spinose Ear Tick (*Otobius megnini*)

Black-legged Tick (*Ixodes scapularis*)

Tropical Bont Tick (*A. variegatum*)

Cayenne Tick (*A. cajennense*)

Cattle Tick (*Boophilus annulatus*)

Southern Cattle Tick (*B. microplus*)

Biting Louse (*Damalinia bovis*)

Sucking Lice (*Haematopinus eurysternus*, *Linognathus vituli*, *Solenopotes capillatus*)

MITES

Scab and Mange Mites (*Chorioptes bovis*, *Psoroptes ovis* and *Sarcoptes scabiei* var. *bovis*)

Spray:

For control of ticks and lice, mix one can (760 ml) of TAKTIC® E.C. in 100 gallons of water; for control of mites, mix one can of TAKTIC® E.C. in 50 gallons of water. Use Taktic® solutions within 6 hours of mixing. Use up to 2 gallons of spray for a fully grown animal. It is important to wet the animal thoroughly and that the spray penetrates to the skin until run-off. For Lone Star ticks, cattle ticks, sucking lice and chewing lice, particular attention

should be given to the legs, axilla and groin area, udder, tail regions and head, including the ears. For Gulf Coast ticks and ear ticks, treat the head, ears, shoulder area and neck with a low pressure spray. For control of lice, a second treatment 10-14 days later is recommended, to kill lice hatching from eggs.

Spray Dip Machine:

For control of ticks and lice, mix one can (760 ml) of TAKTIC® E.C. in 100 gallons of water; for control of mites, mix one can of TAKTIC® E.C. in 50 gallons of water. To control cattle scabies, applications should be made as instructed by USDA, APHIS, VS bulletins. Two treatments 7-10 days apart are required to control cattle scabies. Use Taktic® solutions within 6 hours of mixing. Use up to 2 gallons of spray for a fully grown animal. It is important to wet the animal thoroughly and that the spray penetrates to the skin until run-off.

SWINE

MANGE MITE AND LOUSE (*Sarcoptes scabiei* var. *swis* and *Haematopinus suis*):

IMPORTANT

Remove feed from pen and cover drinking bowls. Remove and destroy bedding. Hose out feces and excess feed. Use TAKTIC® solutions within 6 hours of mixing.

Spray:

Mix one can (760 ml) TAKTIC® E.C. in 50 gallons of water (equivalent to 1/2 fl. ounce per gallon of spray solution). A sprayer with a coarse nozzle delivering the solution at 70 to 150 psi is recommended. Spray the walls, floor and any fittings in the pen. Spray all animals (at the same time) whether visibly affected or not. Spray the animals until the mixture runs off, paying particular attention to treat the jowl, legs, inside the ears and underside of the body. It is important that the spray penetrates to the skin until run-off. A second treatment is recommended to break the parasites' life cycles. Make the application 7-10 days after the first treatment for mite control, and 10-14 days for lice control.

An alternate to spraying young pigs (piglets/weaners) is to dip them in a suitable-sized container. Dip 30 animals and then replace dip wash. Use dip wash to treat premises.

Do not treat animals more than 4 times per year.

Do not apply to swine within three days of slaughter.

Do not use Taktic® E.C. at the same time with any other amitraz containing product.

IMPORTANT NOTICE: DISCLAIMER

Read "IMPORTANT NOTICE: DISCLAIMER" before buying or using. If terms are not acceptable, return at once unopened. HOECHST ROUSSEL VET warrants only that the product conforms to the chemical description on the label and is reasonably fit for the purpose stated on the label when used in accordance with the directions under normal conditions of use. This warranty does not extend to the use of this product contrary to label instructions or under abnormal conditions, or under conditions not reasonably foreseeable to HOECHST ROUSSEL VET, and user assumes the risk of any such use. HOECHST ROUSSEL VET MAKES NO OTHER WARRANTY, EXPRESSED OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE OR OF MERCHANTABILITY. In no case shall HOECHST ROUSSEL VET be liable for consequential, special, indirect or incidental damages resulting from the use or handling of this product. The foregoing conditions of sale and warranty can be varied only by agreement in writing signed by a duly authorized representative of HOECHST ROUSSEL VET.

Taktic (amitraz) is a registered trademark of Hoechst Roussel Vet GmbH. The name and logo HOECHST are registered trademarks of HOECHST AG.

©1998 HR Vet

584350-5/98 MADE IN CANADA NET CONTENTS: 760 ml (23.7 fl. oz.)

Telefax Transmittal
Cover sheet



Intervet Inc.
405 State Street
P.O. Box 318
Millsboro, DE 19966
(302) 934-8051

September 7, 2001

6...pages including cover sheet.

PERSON TO:	COMPANY/DEPT TO:	FAX NUMBER:
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Dr. Akiva Abramovitch

Environmental Protection Agency
Insecticide-Rodenticide Branch
Registration Division (7505C)

703-305-8598

PERSON FROM:	COMPANY/DEPT FROM:	FAX NUMBER:
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S. Lee Whaley, MS
Manager, Regulatory Affairs -
Pharmaceuticals

Intervet Inc.
Millsboro, Delaware

Fax: 302-934-4209
Phone: 302-934-4385

RE: Taktic EC (Amitraz); EPA Registration No. 54382-3

Dear Dr. Abramovitch,

This fax follows our conversation this morning regarding the above-mentioned product and provides you a copy of the 27 April 1999 letter from Mr. Leonard Cole (EPA). The 27 April 1999 letter includes a copy of the EPA-stamped label incorporating the changes required by the amitraz re-registration eligibility decision (RED). Please feel free to contact me by phone (302-934-4385) or e-mail (lee.whaley@intervet.com) if I can be of further assistance.

Sincerely,

S. Lee Whaley, MS

(Manager, Regulatory Affairs - Pharmaceuticals; Intervet Inc.)

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE INDIVIDUAL OR ENTITY TO WHICH IT IS ADDRESSED, AND MAY CONTAIN PROPRIETARY INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND EXEMPT FROM DISCLOSURE UNDER APPLICABLE LAW. IF YOU ARE NOT THE ADDRESSEE, YOU ARE HEREBY NOTIFIED THAT ANY DISSEMINATION, DISTRIBUTION, OR COPYING OF THIS COMMUNICATION IS STRICTLY PROHIBITED. IF YOU HAVE RECEIVED THIS COMMUNICATION IN ERROR, NOTIFY US IMMEDIATELY BY TELEPHONE (COLLECT). THANK YOU.

rec'd 4/28/99**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

APR 27 1999

John L. Lauber, Ph.D.
Hoechst Roussel Vet
30 Independence Blvd.
P.O. Box 4915
Warren, New Jersey 07059-0915

Dear Dr. Lauber:

Subject: Labeling Amendment
Taktic EC
EPA Registration No. 54382-3
Your submission dated 31 March 1999

The labeling amendment referred to above submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, has been received and reviewed, and the labeling is acceptable. Please submit three (3) copies of your final printed labeling incorporating the changes prior to releasing your product for shipment. A stamped copy is enclosed for your records.

Sincerely,

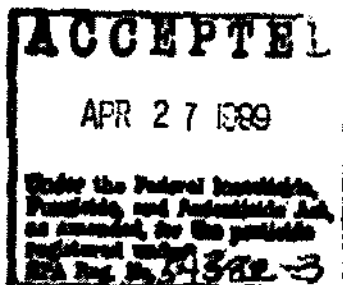
A handwritten signature in cursive script, appearing to read "Leonard Cole".

Leonard Cole
Insecticide-Rodenticide Branch
Registration Division (7505C)

Enclosure

Label C -- Proposed Label

January 11, 1999, 4 pages



This product contains Petroleum Distillate. →

Taktic®

EMULSIFIABLE CONCENTRATE
MITICIDE/INSECTICIDE



FOR THE CONTROL OF MITES AND INSECTS ON
CATTLE, SHEEP, CATS, DOGS, HORSES AND PIGS

ACTIVE INGREDIENT

Amalgam

INERT INGREDIENTS

See Statement of Practical Treatment on Back Label

KEEP OUT OF REACH OF CHILDREN
DANGER-PELIGRO

SEE STATEMENT OF PRACTICAL
TREATMENT ON BACK LABEL

KEEP OUT OF REACH OF CHILDREN

DANGER-PELIGRO

SEE STATEMENT OF PRACTICAL
TREATMENT ON BACK LABEL

Hoechst Roux U.S.A. Inc.

Hoechst

NET CONTENTS: 760 ml (25.7 fl. oz.)

STATEMENT OF PRACTICAL TREATMENT (FIRST AID):

(B) →

CONTINGENCY CENTER IMMEDIATELY. IT IS NOT PERMISSIBLE TO USE GASTRIC LAVAGE UNDER MEDICAL SUPERVISION DUE TO ASPIRATION HAZARD. DO NOT INDUCE VOMITING OR GIVE ANYTHING BY MOUTH TO AN UNCONSCIOUS PERSON. MALAZ is NOT AN ORGANOPHOSPHORUS COMPOUND. DO NOT USE ATROPINE OR PENTHOTO. IF IN EYES: FLUSH WITH PLENTY OF WATER. GET MEDICAL ATTENTION. IF ON SKIN: WASH WITH SOAP AND WATER.

PRECAUTIONARY STATEMENTS
 Hazards to Humans (and Domestic Animals)

DANGER

(C) →

absorbed through skin. Repeated skin contact may cause an allergic reaction in certain individuals.

Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

Personal Protective Equipment (PPE)

Applicators and other handlers must wear:

Chemical-resistant apron over long-sleeved shirt and long pants.

Chemical-resistant footwear plus socks.

Chemical-resistant gloves.

Chemical-resistant headgear for overhead exposure.

Goggles or face shield, and chemical-resistant apron when cleaning equipment, mixing or loading.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.

For livestock spray or dip applications in enclosed areas: Apply only in well-ventilated areas.

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions exist for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

User Safety Recommendations

- Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish and aquatic invertebrates. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean water mark. Drift and runoff from treated areas may be hazardous to aquatic organisms in adjacent sites. Do not contaminate water when disposing of equipment washwaters or rinsate.

PHYSICAL OR CHEMICAL HAZARDS

Do not use or store near heat or open flame.

STORAGE AND DISPOSAL

STORAGE: Not for storage in and around the home environment. Store in original container in a locked dry place. Do not open the container until ready to use. Use entire contents of can when opened. Keep from freezing.

IF IN EYES: Hold eyelids open and flush with steady, gentle stream of water for 15 minutes. Get medical attention.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention.

IF INHALED: Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical attention.

IF SWALLOWED: Call a physician or Poison Control Center. Do not induce vomiting. Drink promptly a large quantity of milk, egg whites, gelatin solution, or if these are not available, drink large quantities of water. Avoid alcohol.

NOTE TO PHYSICIAN:

Amitraz, the active ingredient in this product, is not an organophosphorus compound. Do not use atropine as an antidote. Treat any overexposure symptomatically. Mucosal damage is probable which increases the risk of gastric lavage. The presence of petroleum distillate in this product may pose an aspiration pneumonia hazard.

Corrosive. Causes irreversible eye damage. Causes skin irritation. Harmful if swallowed or absorbed through skin or inhaled. Do not get in eyes, on skin or on clothing. Avoid breathing spray mist. Wear goggles or face shield. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

PESTICIDE DISPOSAL: Do not contaminate water, food or feed by storage or disposal. Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of federal law. If these wastes cannot be disposed of by use according to label instructions, contact your state pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

In case of spillage, cover with an absorbent such as soda ash, clay or sawdust. Sweep up and dispose of as directed under Storage and Disposal.

DO NOT REUSE EMPTY CONTAINER.

EMERGENCY PHONE NOS.:

HUMAN, FIRE, SPILLS, ENVIRONMENTAL:
1-800-220-6838, Ext. 132

ANIMALS: 1-800-345-4735, Ext. 104

DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

DO NOT USE ON HORSES or DOGS - CAN CAUSE DEATHS.

DO NOT OPEN CONTAINER UNTIL READY TO USE.

USE TAKTIC® E.C. WITH WATER ONLY. DO NOT MIX WITH OIL OR OTHER SOLVENTS.

BEEF AND DAIRY CATTLE

TAKTIC® E.C. can be used on lactating dairy animals, with no withholding period for milk following application. Also, there is no post-treatment slaughter interval on beef and dairy cattle.

TICKS AND LICE:

TAKTIC® E.C. will control the following Ticks and Lice on cattle:

Lone Star Tick (*Amblyomma americanum*)

Gulf Coast Tick (*A. maculatum*)

Winter Tick (*Dermacentor albipictus*)

Brown Dog Tick (*Rhipicephalus sanguineus*)

American Dog Tick (*D. variabilis*)

Rocky Mountain Wood Tick (*Dermacentor andersoni*)

Spinose Ear Tick (*Otobius megnini*)

Black-legged Tick (*Ixodes scapularis*)

Tropical Bont Tick (*A. variegatum*)

Cayenne Tick (*A. cajennense*)

Cattle Tick (*Boophilus annulatus*)

Southern Cattle Tick (*B. microplus*)

Biting Louse (*Haematopinus bovis*)

Sucking Lice (*Haematopinus eurysternus*, *Linognathus vituli*, *Solenopotes capillatus*)

MITES

Scab and Mange Mites (*Chorioptes bovis*, *Psoroptes ovis* and *Sarcoptes scabiei* var. *bovis*)

Spray:

For control of ticks and lice, mix one can (760 ml) of TAKTIC® E.C. in 100 gallons of water; for control of mites, mix one can of TAKTIC® E.C. in 50 gallons of water. Use Taktic® solutions within 6 hours of mixing. Use up to 2 gallons of spray for a fully grown animal. It is important to wet the animal thoroughly and that the spray penetrates to the skin until run-off. For Lone Star ticks, cattle ticks, sucking lice and chewing lice, particular attention

should be given to the legs, axilla and groin area, udder, tail regions and head, including the ears. For Gulf Coast ticks and ear ticks, treat the head, ears, shoulder area and neck with a low pressure spray. For control of lice, a second treatment 10-14 days later is recommended, to kill lice hatching from eggs.

Spray Dip Machine:

For control of ticks and lice, mix one can (760 ml) of TAKTIC® E.C. in 100 gallons of water; for control of mites, mix one can of TAKTIC® E.C. in 50 gallons of water. To control cattle scabies, applications should be made as instructed by USDA, APHIS, VS bulletin. Two treatments 7-10 days apart are required to control cattle scabies. Use Taktic® solutions within 6 hours of mixing. Use up to 2 gallons of spray for a fully grown animal. It is important to wet the animal thoroughly and that the spray penetrates to the skin until run-off.

SWINE

MANGE MITE AND LOUSE (*Sarcoptes scabiei* var. *swine* and *Haematopinus suis*):

IMPORTANT

Remove feed from pen and cover drinking bowls. Remove and destroy bedding. Hose out faces and excess feed. Use TAKTIC® solutions within 6 hours of mixing.

Spray:

Mix one can (760 ml) TAKTIC® E.C. in 50 gallons of water (equivalent to 1/2 fl. ounce per gallon of spray solution). A sprayer with a coarse nozzle delivering the solution at 70 to 150 psi is recommended. Spray the walls, floor and any things in the pen. Spray all animals (at the same time) whether visibly affected or not. Spray the animals until the mixture runs off, paying particular attention to treat the jaw, legs, inside the ears and underside of the body. It is important that the spray penetrates to the skin until run-off. A second treatment is recommended to break the parasites' life cycles. Make the application 7-10 days after the first treatment for mite control, and 10-14 days for lice control.

An alternate to spraying young pigs (piglets/weaners) is to dip them in a suitable-sized container. Dip 30 animals and then replace dip wash. Use dip wash to treat premises.

Do not treat animals more than 4 times per year.

Do not apply to swine within three days of slaughter.

Do not use Taktic® E.C. at the same time with any other antiparasitic containing product.

IMPORTANT NOTICE: DISCLAIMER

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Taktic (antitick) is a registered trademark of Hoechst Roussel Vet GmbH. The name and logo HOECHST are registered trademarks of HOECHST AG.

©1998 HV Vet
304380-0/08 MADE IN CANADA NET CONTENTS: 760 ml (25.7 fl. oz.)

Telefax Transmittal
Cover sheet



Intervet Inc.
405 State Street
P.O. Box 318
Millsboro, DE 19966
(302) 934-8051

September 7, 2001

6...pages including cover sheet.

PERSON TO:	COMPANY/DEPT TO:	FAX NUMBER:
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Dr. Akiva Abramovitch

Environmental Protection Agency
Insecticide-Rodenticide Branch
Registration Division (7505C)

703-305-6596

PERSON FROM:	COMPANY/DEPT FROM:	FAX NUMBER:
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S. Lee Whaley, MS
Manager, Regulatory Affairs -
Pharmaceuticals

Intervet Inc.
Millsboro, Delaware

Fax: 302-934-4209
Phone: 302-934-4385

RE: Taktic EC (Amitraz); EPA Registration No. 54382-3

Dear Dr. Abramovitch,

This fax follows our conversation this morning regarding the above-mentioned product and provides you a copy of the 27 April 1999 letter from Mr. Leonard Cole (EPA). The 27 April 1999 letter includes a copy of the EPA-stamped label incorporating the changes required by the amitraz re-registration eligibility decision (RED). Please feel free to contact me by phone (302-934-4385) or e-mail (lee.whaley@intervet.com) if I can be of further assistance.

Sincerely,

S. Lee Whaley, MS

(Manager, Regulatory Affairs - Pharmaceuticals; Intervet Inc.)

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE INDIVIDUAL OR ENTITY TO WHICH IT IS ADDRESSED, AND MAY CONTAIN PROPRIETARY INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND EXEMPT FROM DISCLOSURE UNDER APPLICABLE LAW. IF YOU ARE NOT THE ADDRESSEE, YOU ARE HEREBY NOTIFIED THAT ANY DISSEMINATION, DISTRIBUTION, OR COPYING OF THIS COMMUNICATION IS STRICTLY PROHIBITED. IF YOU HAVE RECEIVED THIS COMMUNICATION IN ERROR, NOTIFY US IMMEDIATELY BY TELEPHONE (COLLECT). THANK YOU.

recd 4/28/99

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

APR 27 1999

John L. Lauber, Ph.D.
Hoechst Roussel Vet
30 Independence Blvd.
P.O. Box 4915
Warren, New Jersey 07059-0915

Dear Dr. Lauber:

Subject: Labeling Amendment
Taktic EC
EPA Registration No. 54382-3
Your submission dated 31 March 1999

The labeling amendment referred to above submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, has been received and reviewed, and the labeling is acceptable. Please submit three (3) copies of your final printed labeling incorporating the changes prior to releasing your product for shipment. A stamped copy is enclosed for your records.

Sincerely,

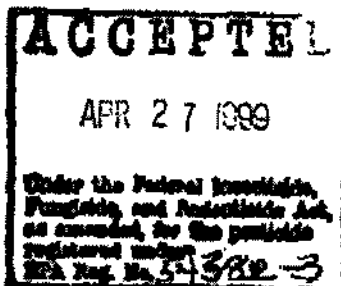
A handwritten signature in black ink, appearing to read "Leonard Cole".

Leonard Cole
Insecticide-Rodenticide Branch
Registration Division (7505C)

Enclosure

Label C -- Proposed Label

January 11, 1999, 4 pages



This product contains Petroleum Distillate. →

Taktic®

EMULSIFIABLE CONCENTRATE MITICIDE/INSECTICIDE



FOR THE CONTROL OF TICKS, MANGE MITES AND
LICE ON BEEF CATTLE, DAIRY CATTLE AND SWINE

DO NOT USE ON CATTLE OR HORSES THAT CAUSE FATAL CALICULUS (WOUND)

ACTIVE INGREDIENT:	Percent by Weight
Amtraz	12.5
INERT INGREDIENTS	87.5
	TOTAL 100%

This product contains 5% (w/v) petroleum distillate

EPA Reg. No. 54382-3

EPA EST. NO. 0-00-000001

U.S. Patent Nos. 3,731,355 and 3,561,497

PRECAUCION AL USUARIO: Se usará en las regiones de uso solo productivo
pasto due to enquistamiento y/o aplicación incorrecta

(TO THE USER: If you cannot read English, do not use this
product until the label has been fully explained to you.)

KEEP OUT OF REACH OF CHILDREN

ANGER-PELIGRO

SEE STATEMENT OF PRACTICAL
TREATMENT ON BACK LABEL

Hoechst Roussel Vet

Amtraz 12.5% EC

Amtraz 12.5% EC

Amtraz 12.5% EC

For more information, contact your local distributor or
Hoechst Roussel Vet, P.O. Box 1000, Kenilworth, NJ 07033

Hoechst

Amtraz 12.5% EC

NET CONTENTS: 760 ml (25.7 fl. oz.)

STATEMENT OF PRACTICAL TREATMENT (FIRST AID):

(B) →

CONTROL CENTER IMMEDIATELY. IT IS PREFERABLE TO USE GASTRIC LAVAGE UNDER MEDICAL SUPERVISION DUE TO ASPIRATION HAZARD. DO NOT INDUCE VOMITING OR GIVE ANYTHING BY MOUTH TO AN UNCONSCIOUS PERSON. MEVIAZ IS NOT AN ORGANOPHOSPHORUS COMPOUND. DO NOT USE ATROPINE AS AN ANTIDOTE.

IF IN EYES: FLUSH WITH PLENTY OF WATER. GET MEDICAL ATTENTION.

IF ON SKIN: WASH WITH SOAP AND WATER.

PRECAUTIONARY STATEMENTS
 Hazards to Humans (and Domestic Animals)

DANGER

(C) →

absorbed through skin. Repeated skin contact may cause an allergic reaction in certain individuals.

Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

Personal Protective Equipment (PPE)

Applicators and other handlers must wear:

Chemical-resistant apron over long-sleeved shirt and long pants.

Chemical-resistant footwear plus socks.

Chemical-resistant gloves.

Chemical-resistant headgear for overhead exposure.

Goggles or face shield, and chemical-resistant apron when cleaning equipment, mixing or loading.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.

For livestock spray or dip applications in enclosed areas: Apply only in well-ventilated areas.

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions exist for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

User Safety Recommendations

- Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish and aquatic invertebrates. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean water mark. Drift and runoff from treated areas may be hazardous to aquatic organisms in adjacent sites. Do not contaminate water when disposing of equipment washwaters or rinsate.

PHYSICAL OR CHEMICAL HAZARDS

Do not use or store near heat or open flame.

STORAGE AND DISPOSAL

STORAGE: Not for storage in and around the home environment. Store in original container in a locked dry place. Do not open the container until ready to use. Use entire contents of can when opened. Keep from freezing.

IF IN EYES: Hold eyelids open and flush with steady, gentle stream of water for 15 minutes. Get medical attention.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention.

IF INHALED: Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical attention.

IF SWALLOWED: Call a physician or Poison Control Center. Do not induce vomiting. Drink promptly a large quantity of milk, egg whites, gelatin solution, or if these are not available, drink large quantities of water. Avoid alcohol.

NOTE TO PHYSICIAN:

Amitraz, the active ingredient in this product, is not an organophosphorus compound. Do not use atropine as an antidote. Treat any overexposure symptomatically. Mucosal damage is probable which increases the risk of gastric lavage. The presence of petroleum distillate in this product may pose an aspiration pneumonia hazard.

Corrosive. Causes irreversible eye damage. Causes skin irritation. Harmful if swallowed or absorbed through skin or inhaled. Do not get in eyes, on skin or on clothing. Avoid breathing spray mist. Wear goggles or face shield. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

PESTICIDE DISPOSAL: Do not contaminate water, food or feed by storage or disposal. Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of federal law. If these wastes cannot be disposed of by use according to label instructions, contact your state pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

In case of spillage, cover with an absorbent such as soda ash, clay or sawdust. Sweep up and dispose of as directed under Storage and Disposal.

DO NOT REUSE EMPTY CONTAINER.

EMERGENCY PHONE NOS.:

HUMAN, FIRE, SPILLS, ENVIRONMENTAL:
1-800-228-5835, Ext. 132

ANIMALS: 1-800-345-4735, Ext. 104

DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

DO NOT USE ON HORSES or DOGS - CAN CAUSE DEATHS.

DO NOT OPEN CONTAINER UNTIL READY TO USE.

USE TAKTIC® E.C. WITH WATER ONLY. DO NOT MIX WITH OIL OR OTHER SOLVENTS.

BEEF AND DAIRY CATTLE

TAKTIC® E.C. can be used on lactating dairy animals, with no withholding period for milk following application. Also, there is no post-treatment slaughter interval on beef and dairy cattle.

TICKS AND LICE:

TAKTIC® E.C. will control the following Ticks and Lice on cattle:

Lone Star Tick (*Amblyomma americanum*)

Gulf Coast Tick (*A. maculatum*)

Winter Tick (*Dermacentor albipictus*)

Brown Dog Tick (*Rhipicephalus sanguineus*)

American Dog Tick (*D. variabilis*)

Rocky Mountain Wood Tick (*Dermacentor andersoni*)

Spinose Ear Tick (*Otobius megnini*)

Black-legged Tick (*Ixodes scapularis*)

Tropical Bont Tick (*A. variegatum*)

Cayenne Tick (*A. cajennense*)

Cattle Tick (*Boophilus annulatus*)

Southern Cattle Tick (*B. microplus*)

Biting Louse (*Damalinia bovis*)

Sucking Lice (*Haematopinus eurysternus*, *Linognathus vituli*, *Solenopotes capillatus*)

MITES

Scab and Mange Mites (*Chorioptes bovis*, *Psoroptes ovis* and *Sarcoptes scabiei* var. *bovis*)

Spray:

For control of ticks and lice, mix one can (760 ml) of TAKTIC® E.C. in 100 gallons of water; for control of mites, mix one can of TAKTIC® E.C. in 50 gallons of water. Use Taktic® solutions within 6 hours of mixing. Use up to 2 gallons of spray for a fully grown animal. It is important to wet the animal thoroughly and that the spray penetrates to the skin until run-off. For Lone Star ticks, cattle ticks, sucking lice and chewing lice, particular attention

should be given to the legs, axilla and groin area, udder, tail regions and head, including the ears. For Gulf Coast ticks and ear ticks, treat the head, ears, shoulder area and neck with a low pressure spray. For control of lice, a second treatment 10-14 days later is recommended, to kill lice hatching from eggs.

Spray Dip Machine:

For control of ticks and lice, mix one can (760 ml) of TAKTIC® E.C. in 100 gallons of water; for control of mites, mix one can of TAKTIC® E.C. in 50 gallons of water. To control cattle scabies, applications should be made as instructed by USDA, APHIS, VS bulletin. Two treatments 7-10 days apart are required to control cattle scabies. Use Taktic® solutions within 6 hours of mixing. Use up to 2 gallons of spray for a fully grown animal. It is important to wet the animal thoroughly and that the spray penetrates to the skin until run-off.

SWINE

MANGE MITE AND LOUSE (*Sarcoptes scabiei* var. *suis* and *Haematopinus suis*):

IMPORTANT

Remove feed from pen and cover drinking bowls. Remove and destroy bedding. Hose out feces and excess feed. Use TAKTIC® solutions within 6 hours of mixing.

Spray:

Mix one can (760 ml) TAKTIC® E.C. in 50 gallons of water (equivalent to 1/2 fl. ounce per gallon of spray solution). A sprayer with a coarse nozzle delivering the solution at 70 to 150 psi is recommended. Spray the walls, floor and any fittings in the pen. Spray all animals (at the same time) whether visibly affected or not. Spray the animals until the mixture runs off, paying particular attention to treat the jaw, legs, inside the ears and underside of the body. It is important that the spray penetrates to the skin until run-off. A second treatment is recommended to break the parasite's life cycles. Make the application 7-10 days after the first treatment for mite control, and 10-14 days for lice control.

An alternate to spraying young pigs (piglets/weaners) is to dip them in a suitable-sized container. Dip 30 animals and then replace dip wash. Use dip wash to treat premises.

Do not treat animals more than 4 times per year.

Do not apply to swine within three days of slaughter.

Do not use Taktic® E.C. at the same time with any other amitraz containing product.

IMPORTANT NOTICE: DISCLAIMER

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©1996 HRI Vet
584350-5/96 MADE IN CANADA NET CONTENTS: 760 ml (23.7 fl. oz.)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

SEP 22 1998

John J. Lauber, Ph.D.
Hoechst Roussel Vet
P.O. Box 2500
Somerville, New Jersey 08876-1258

Dear Dr. Lauber:

Subject: Labeling Requirements for Reregistration
Tactic E.C.
EPA Reg. No. 54382-3
Your submission dated 16 September 1997

The labeling referred to above submitted in connection with reregistration under Section 4 of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, has been received and reviewed, and the following are the Agency's comments:

Precautionary Review Comments

1. You must include on your labeling the phrase "Contains Petroleum Distillate".
2. The signal word for this product is DANGER.
3. The precautionary statements should reflect: Corrosive. Causes irreversible eye damage. Cause skin irritation. Harmful if swallowed or absorbed through skin or inhaled. Do not get in eyes, on skin or on clothing. Avoid breathing spray mist. Wear goggles or face shield. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.
4. The Statement of Practical Treatment (SOPT) "First Aid" should be reflected on the labeling as follows:
5. IF IN EYES: Hold eyelids open and flush with steady, gentle stream of water for 15 minutes. Get medical attention.
6. IF ON SKIN: Wash with plenty of soap and water. Get medical attention.

7. IF INHALED: Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical attention.
8. IF SWALLOWED: Call a physician or Poison Control Center. Do not induce vomiting. Drink promptly a large quantity of milk, egg whites, gelatin solution, or if these are not available, drink large quantities of water. Avoid alcohol.

It is recommended that the proposed labeling should contain a Note to Physicians with the following guidance:

NOTE TO PHYSICIAN:

The proposed label should contain.

Probable mucosal damage may contraindicate the use of gastric lavage.

May pose an aspiration pneumonia hazard.

The following are some suggested types of information that could be included, if applicable, in the Note to Physicians:

- technical information on symptomatology;
- use of supportive treatments to maintain life functions;
- medicine that will counteract the specific physiological effects of the pesticide;
- company telephone number to specific medical personnel who can provide specialized medical advice.

Should you have any further questions regarding these amendments to your labeling, you may contact me directly at 703.305.5412.

Sincerely,



Leonard Cole
Insecticide-Rodenticide Branch
Registration Division (7505C)

DP BARCODE: D249399

CASE: 117897
SUBMISSION: S531805

DATA PACKAGE RECORD
BEAN SHEET

DATE: 09/11/98
Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 674 8 MNTH RESP-PROD SPC DATA
RANKING : 0 POINTS ()
CHEMICALS: 106201 Amitraz (ANSI) 12.5000%

ID#: 054382-00003 TAKTIC E.C.
COMPANY: 054382 HOECHST ROUSSEL VET
PRODUCT MANAGER: 04 TINA LEVINE 703-308-7055 ROOM: CM2 219
PM TEAM REVIEWER: CP MORAN 703-308-8590 ROOM: CM2 117 L
RECEIVED DATE: 09/23/97 DUE OUT DATE: 03/22/98

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 249399 EXPEDITE: N DATE SENT: 09/11/98 DATE RET.: / /
CHEMICAL: 106201 Amitraz (ANSI)

DP TYPE: 001 Submission Related Data Package

CSF: Y LABEL: Y
ASSIGNED TO DATE IN DATE OUT ADMIN DUE DATE: 12/10/98
DIV : RD / / / / NEGOT DATE: / /
BRAN: IRB / / / / PROJ DATE: / /
SECT: PM04 / / / /
REVR : / / / /
CONTR: / / / /

* * * DATA REVIEW INSTRUCTIONS * * *

This product is recommended for reregistration upon your final review of the label for compliance with the Amitraz RED. After label review is done, please close this data package submission as well as the 674 submission with a reregistration decision and file all pertinent information in the product jacket.

Attached:

CSFs
Labels
Product Chemistry review
Acute Toxicity reviews
PRB preliminary label assessment
Correspondence/administrative

* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL
240281	TRB/IO	10/28/97	01/26/98	Y	Y	Y
240309	TRB/TOX	10/29/97	11/14/97	Y	Y	Y
241308	PRB/IO	12/04/97	03/04/98	Y	Y	Y



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM:

Date: February 9, 1998

Subject: Data review of product TAKTIC EC for acute eye irritation (81-4), and
dermal sensitization (81-6)
EPA Reg. No.: 54382-3
MRID Nos.: 44388508, 44388510
DP Barcode: D242206

From: Hari Mukhoty, DVM, PhD (Secondary review by Ian Blackwell) *2/12/98*
Product Reregistration Branch (PRB) *2/12/98*
Special Review and Reregistration Division (SRRD), Mail Code: 7508W

To: C.P. Moran, CRM
PRB, SRRD, Mail Code: 7508W

Applicant: Hoechst Roussel Vet
P.O. Box 4915
30 Independence Blvd.
Warren, NJ 07059

FORMULATION FROM LABEL:

Active Ingredient: % by wt.	
Amitraz.....	12.9
Inert Ingredients.....	87.1
<hr/>	
Total.....	100.0

BACKGROUND:

Hoecht Roussel Vet has submitted data on primary eye irritation and dermal sensitization studies for Amitraz-based insecticide product with the trade name TAKTIC EC. The company is asking the Agency to evaluate the studies as to their acceptability in satisfying the 81-4, and 81-6 data requirements for reregistration. The data for the remaining four acute toxicity studies are currently being reviewed by the contractor on Bean Sheet No. D240309. This is a 6 (a) (2) review for primary eye irritation and dermal sensitization effects of TAKTIC EC (ISB/IRSD Request for 6 (a) (2) screen document dated October 23, 1997).

RECOMMENDATION:

Studies submitted for acute eye irritation and dermal sensitization are acceptable.

The acute toxicity profile for product Reg. No. 54382-3 is currently:

Primary eye irritation	I	Acceptable
Dermal sensitization	Sensitizer	Acceptable

LABELING:

Labeling shall be provided when review of the remaining 4 acute toxicity studies is complete.

DATA REVIEW FOR DERMAL SENSITIZATION TESTING (Series 81-6 / 870.2600)

Product Manager: Tina Levine, 4
MRID No.: 44388510

Reviewer: Hari Mukhoty
Study completion date: August 28, 1997
Report No.: 96-0029

Testing Laboratory: Springborn Laboratories, Inc.
Author: Deborah A. Douds

Quality Assurance (40 CFR Part 160.12): included

Test Material: Taktic E.C., EPA Reg. No.: 54382-3 (yellow liquid)
Positive control material: DNCB

Species: Hartley albino guinea pigs
Weight: 332-433 grams. Age: not provided
Source: Harlan Sprague Dawley, Inc.

Method: Modified Buehler method

Summary:

- 1. This product is a dermal sensitizer.**
- 2. Classification: acceptable**

PROCEDURE & RESULTS:

Two range-finding tests were conducted, and each test used four (2 males & 2 females) young adult guinea pigs. The first test used test material at concentrations of 25 %, 50 %, 75 %, and 100 % w/v in deionized water, and all the animals showed severe dermal irritation ranging from redness to edema. Therefore, a second test was performed with lower concentrations (5 %, 10 %, 15 %, and 20 % w/v in deionized water) of the test material. In the second test, only few animals showed slight redness of the skin.

For induction study, ten animals were topically treated with 0.3 mL of 50 % w/v of the test material in deionized water, once per week, for three consecutive weeks. Following a two-week rest period, a challenge test was performed with 10 test-material induced animals and ten previously untreated challenge control guinea pigs. These animals were exposed with 0.3mi of 20 % solution of test material for 6 hours. Irritation responses were scored approximately 24 and 48 hours after treatment in all three phases of both induction and challenge tests. Dermal irritation ranging from redness (slight patchy & confluent, moderate patchy & confluent) to edema was noticeable in most animals in all induction phases. Following challenge, redness (dermal scores: 1 to 2- slight patchy, slight confluent, moderate

patchy, moderate confluent) and slight edema were noted in some animals at the 24 and 48 hour scoring interval. Group mean dermal scores were noted to be higher in the test animals as compared with the challenge control animals.

DNCB control group received 0.3 mL of 0.1 % w/v DNCB in acetone/ethanol for induction and 0.1 % and 0.05 % w/v DNCB in acetone/ethanol for challenge. Following challenge, 10/10 DNCB test animals were noted to have a substantially stronger dermal response than was observed in the corresponding DNCB control animals.

CONCLUSION:

(a). The test product produced various degrees of dermal reaction during the induction phase (slight patchy & confluent redness, moderate patchy & confluent erythema, very slight to slight edema with edges area well defined by definite raising)

(b). Dermal sensitization reactions, ranging from redness to edema, were observed following challenge with the test substance. Group mean dermal scores were noted to be higher in the test animals as compared with the challenge control animals.

(c). DNCB positive control animals showed dermal reactions following each of the inductions; and positive responses occurred after challenge. Following challenge with DNCB, 10/10 DNCB test animals were noted to have a substantially stronger dermal response than was observed in the corresponding DNCB control animals.

The dermal reaction observed in this study adequately demonstrate that test product, Reg. No.54382-3, is a contact sensitizer in guinea pig. This study is classified as acceptable. This study (MRID 44388510) satisfy the 81-6 data requirement for the above referenced product.

RESULTS:

OBSERVATIONS	(number "positive"/number tested)							
	Hours				Days			
	1	24	48	72	7	10	14	21
Corneal Opacity	6/6	6/6	5/6	5/6	5/6	3/6	2/6	2/6
Iris	6/6	5/6	4/6	4/6	2/6	2/6	1/6	1/6
Conjunctivae								
Redness	6/6	6/6	6/6	6/6	3/6	1/6	1/6	1/6
Chemosis	6/6	6/6	5/6	5/6	2/6	1/6	1/6	1/6
Discharge	6/6	6/6	4/6	2/6	0/6	0/6	0/6	0/6

ACUTE TOX ONE-LINER

1. PC CODE: 106201
2. CURRENT DATE: February 9, 1998
3. TEST MATERIAL: TAKTIC E.C. (Amitraz 12.9%) EPA Reg. No. 054382-3

Data for acute oral, dermal, inhalation toxicity, and skin irritation are currently being reviewed by the contractor.

Study/Species/ Lab/Study#/Date	MRID #	Results	Tox. Cat.	Core Grade
acute oral toxicity		LD ₅₀ males mg/kg females mg/kg combined mg/kg		
acute dermal toxicity		LD ₅₀ >2000 mg/kg limit test		
acute inhalation toxicity/		LC ₅₀ males mg/L females mg/L combined mg/L		
primary eye irritation/rabbit/Springborn Lab. Inc./96-0027/2-21-97	44388508	Corneal opacity resolved in 4/6 by day 14. Iritis resolved in 5/6 by day 14. Redness, chemosis & discharge at 1hr on 6/6 continued past 72 hours.	I	A
primary dermal irritation/				
skin sensitization/rabbit/Springborn Lab. Inc. /96-0029/ 3-7-97	44388510	dermal sensitizer	-----	A

Core Grade Key:

- A = Acceptable
- S = Supplementary (upgradeable)
- U = Unacceptable
- V = self-Validated

DATA REVIEW FOR PRIMARY EYE IRRITATION TESTING (Series 81-4, 870.2400)

Product Manager: Tina Levine, 4
MRID No.: 44388508

Reviewer: Hari Mukhoty
Study completion date: August 28, 1997
Report No.: 96-0027

Testing Laboratory: Springborn Laboratories, Inc.
Author: Deborah A. Douds

Quality Assurance (40 CFR Part 160.12): included

Test Material: Taktic E.C., EPA Reg. No.: 54382-3 (yellow liquid)
Dosage: 0.1 mL

Species: New Zealand White rabbits.
Weight: 332-433 grams. **Age:** not provided.
Source: Myrtle's Rabbitry

Summary:

- 1. Toxicity Category:** I
- 2. Classification:** acceptable

PROCEDURE AND OBSERVATION:

The eyes were macroscopically examined with the aid of an auxiliary light source for signs of irritation at 1, 24, 48, and 72 hours and up to 21 days after dosing according to the Ocular Grading System which is based on Draize. Fluorescein examination was also done to check the affected eyes. Some animals vocalized following dosing, and hair loss was noticed in few animals around and under the right eye.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

June 12, 1998

MEMORANDUM:

Subject: EPA Reg. No.: 54382-03/Taktic E.C.
DP Barcode: D246167
Case No.: 0234

From: Marianne Lewis, Biologist
Product Reregistration Branch
Special Review and Reregistration Division (7508W)

Marianne Lewis 6/15/98
Jim Blackwell

To: C.P.Moran, CRM
Product Reregistration Branch
Special Review and Reregistration Division (7508W)

Applicant: Hoechst Roussel Vet
P.O.Box 4915
30 Independence Blvd.
Warren, NJ 07059

FORMULATION FROM EPA Reg. No. 54382-03 LABEL:

	<u>% by wt.</u>
<u>Active Ingredient(s):</u>	
Amitraz (N'-(2,3-dimethylphenyl)-N-[[2,3-dimethylphenylimino]methyl]-N-methylmethanimidamide)	12.5%
<u>Inert Ingredient(s):</u>	<u>87.5%</u>
Total	100.0%

BACKGROUND: In the 8 month response to the Amitraz RED the registrant has submitted acute toxicity studies to support the reregistration of their product, EPA Reg. No. 54382-03. The MRID's are as follows: 4438850-05 (81-1), 443885-06 (81-2), 443885-07 (81-3), 443885-08 (81-4), 443885-09 (81-5), 443885-10 (81-6). The studies were conducted by Springborn Laboratories, Inc. The material used in the studies was Taktic E.C. Miticide Insecticide, EPA Reg. No. 54382-03. Four (81-1, 81-2, 81-3, 81-5) of the acute toxicity studies were reviewed for PRB by Oak Ridge National Laboratory, an EPA contractor. The primary eye irritation study (81-4) and the skin sensitization study (81-6) were reviewed and accepted by PRB/SRRD, 2/12/98. The four (81-1, 81-2, 81-3, 81-5) studies reviewed are acceptable to support the reregistration of EPA Reg. No. 54382-03.

RECOMMENDATIONS: All of the submitted acute toxicity studies are acceptable to support the reregistration of EPA Reg. No. 54382-03.

The procedural deviations found are discussed here:

Acute Inhalation Study (81-3): At the 2.07 mg/L dose the oxygen content of the exposure chamber was inadequate. From the data given in the study the mean air flow rate (L/min) for the 2.07 mg/L exposure was 5.98 L/min. This indicates that it would take approximately 16.72 minutes to replace the air in the chamber and for each hour during the exposure the air would be replaced only 3.59 times. The Guidelines indicate that the air in the chamber must be changed a minimum of 10 times per hour. This ensures that there is an adequate oxygen content of at least 19% in the chamber during the exposure and that the test atmosphere is evenly distributed throughout the chamber. The two doses used were not sufficient to determine the LC₅₀. However, the 2 doses bracket the Toxicity Category III so the Agency will classify this product as Toxicity Category III. Therefore, the number of air changes in the exposure chamber is a minor deviation and will not affect the outcome of the classification of this product.

The acute toxicity profile for EPA Reg. No. 54382-03 is currently:

Acute Oral	III	Acceptable
Acute Dermal	III	Acceptable
Acute Inhalation	III	Acceptable
Primary Eye	I	Acceptable
Primary Dermal	II	Acceptable
Skin Sensitization	skin sensitizer	Acceptable

LABELING:

ID#: 054382-00003

TAKTIC B.C.

RESTRICTED USE CLASSIFICATION RECOMMENDED:

Due to eye irritation toxicity category.

The PM Team should decide if restricted use classification is necessary or if alternative labeling will allay the requirement for restricted use classification.

INGREDIENT LABELING:

Contains Petroleum Distillate.

SIGNAL WORD: DANGER

PRECAUTIONARY STATEMENTS:

Corrosive. Causes irreversible eye damage. Causes skin irritation. Harmful if swallowed or absorbed through skin or inhaled. Do not get in eyes, on skin or on clothing. Avoid breathing spray mist. Wear goggles or face shield. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

STATEMENT OF PRACTICAL TREATMENT (SOPT) "FIRST AID":

IF SWALLOWED: Call a physician or Poison Control Center. Do not induce vomiting. Drink promptly a large quantity of milk, egg whites, gelatin solution, or if these are not available, drink large quantities of water. Avoid alcohol.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention.

IF INHALED: Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical attention.

IF IN EYES: Hold eyelids open and flush with steady, gentle stream of water for 15 minutes. Get medical attention.

PRB recommends that the proposed label should contain a Note to Physicians with the following guidance:

NOTE TO PHYSICIAN:

The proposed label should contain.

Probable mucosal damage may contraindicate the use of gastric lavage.

May pose an aspiration pneumonia hazard.

Note to CRM/PM/Registrant:

Here are some suggested types of information that could be included, if applicable, in the Note to Physicians:

- technical information on symptomatology;
- use of supportive treatments to maintain life functions;
- medicine that will counteract the specific physiological effects of the pesticide;
- company telephone number to specific medical personnel who can provide specialized medical advice.

Observations:

Dosage mg/kg	Time of Death	Observations
2000	1/10 on day 2	reduced feces, rough coat, dehydration, urine stain, dark material around eyes/nose, decreased activity, piloerection, hunched posture, no feces, low food consumption, lacrimation, slow breathing, prostration, cool to touch, hairloss, corneal opacity, distended abdomen, and fecal material in mouth
3500	2/10 on day 1 1/10 on day 2 3/10 on day 3 2/10 on day 4	decreased activity, piloerection, low food consumption, slow/shallow/labored breathing, reduced/no feces, dark material around eyes/nose/mouth, lacrimation, dehydration, urine/fecal stain, cool to touch, wobbly gait, prostration, hunched posture, rough coat, tremors
5000	3/10 on day 1 1/10 on day 2 3/10 on day 3 2/10 on day 4 1/10 on day 7	decreased activity, slow/shallow/labored breathing, lacrimation, prostration, cool to touch, piloerection, urine/fecal stain, dark material around eyes/mouth/nose, rough coat, hunched posture, low food consumption, reduced/no feces, corneal opacity, eyelids partially closed, hairloss around eyes, dehydration, cyanosis

Gross Necropsy:

Dose mg/kg	Gross necropsy observations
2000	Of the survivors; 1 had thickening of mucosa & white raised areas on stomach, 2 had hairloss, 2 had adhesion within abdominal cavity. The one animal that died had abnormal contents of the small intestine/stomach/urinary bladder and the hair coat was wet & matted.
3500	Hairloss was noted in the two animals that survived the study. The animals that died during the study had: abnormal contents of the small intestine/stomach, mottled/dark red lungs, dilated kidney, pale liver, reddened mucosa of stomach, stained stomach mucosa, dark red thymus/throid, abnormal bladder content, dark material on haircoat, wet matted haircoat.
5000	In all test animals at this dose: abnormal contents in small intestine/stomach, mottled/reddened lungs, mottled kidneys, mottled liver, reddened mucosa of stomach, dark red foci on thymus, dark red thyroid, smaller than usual thymus, dark material on haircoat, wet matted haircoat, dried material matted on haircoat.

DATA REVIEW FOR ACUTE DERMAL TOXICITY (§81-2, 870.1100)

Product Manager: Tina Levine, 04
MRID No.: 44388506

Reviewer: Marianne Lewis
Study Completion Date: 8/28/97
Report No.: 3207.32

Testing Laboratory: Springborn Laboratories, Inc.
Author: D.Douds

Quality Assurance (40 CFR § 160.12): Included

Test Material: Taktic E.C.Miticide Insecticide, EPA Reg. No. 54382-3, yellow liquid

Species: New Zealand White Rabbit
Weight: males = 2496-2679 g; females = 2344-2618 g
Age: adult
Source: Myrtle's Rabbitry

Summary:

1. LD₅₀ (mg/kg): males: >2000 mg/kg
 females: >2000 mg/kg
 combined: >2000 mg/kg

2. Tox. Category: III

Classification: Acceptable

Procedure (Deviations From §81-2): none

Results:

Reported Mortality

DOSAGE (mg/kg)	(number deaths/number tested)		
	Males	Females	Combined
2000	0/5	0/5	0/10

Observations: All test animals were unwilling to lift their head from the cage grate unless stimulated. This reaction cleared by the 24 hour observation in all test animals. Other clinical signs included: slow/labored breathing, decreased activity, protruding penis, dilation of vessels in ears, tremors, reduced feces, soft stools, fecal staining, nystagmus, low food consumption, fasciculation, eyelids appeared red and partially closed, animals were cool to touch, dark material around the nose/mouth. These signs cleared in all test animals by day 6. One animal had soft/mucoid stools and fecal staining from day 6 until the end of the study (day 14).

The dermal irritation seen in all test animals throughout the study included: superficial lightening and blanching of up to 50% of the test area, formation of eschar for more than 50%

of test area, desquamation, very slight to moderate/severe erythema and very slight to slight edema. Fissuring was observed in one animal.

Gross Necropsy Findings: One animal had clear fluid filled cysts on the oviduct, however, this is a common observation in this strain of rabbit. Overall, there were no significant changes observed.

DATA REVIEW FOR ACUTE INHALATION TOXICITY TESTING (§81-3, 870.1300)

Product Manager: Tina Levine, 04
MRID No.: 443885-07

Reviewer: Marianne Lewis
Study Completion Date: 8/28/97
Report No.: 3207.33

Testing Laboratory: Springborn Laboratories, Inc.
Author: D.Douds

Quality Assurance (40 CFR §160.12): Included

Test Material: Taktic E.C.Miticide Insecticide, EPA Reg. No. 54382-3, yellow liquid

Species: Sprague-Dawley Crl:CD®BR VAF/Plus® Rat
Weight: males = 253-289 g; females = 221-256 g
Age: young adult
Source: Charles River Laboratories, Inc.

Summary:

1. The estimated LC_{50} (mg/L) is > 0.55 mg/L
2. MMAD (0.55 mg/L): $2.0 \mu m$ GSD (0.55 mg/L): $1.8 \mu m$
MMAD (2.07 mg/L): $2.3 \mu m$ GSD (2.07 mg/L): $1.9 \mu m$
3. Tox. Category: III Classification: Acceptable

Procedure (Deviation From §81-3):

- at 2.07 mg/L exposure there were less than 10 air changes/hour

Results: Reported Mortality

Exposure Concentration	(Number Deaths/Number Tested)		
	Males	Females	Combined
0.55 mg/L	0/5	0/5	0/10
2.07 mg/L	5/5	5/5	10/10

The doses used were not sufficient to determine the LC_{50} . However, the two doses bracket the Toxicity Category III and enough information was available in this study to determine the Toxicity Category.

Chamber Atmosphere			
Dose Level	MMAD	GSD	% particles <4.0 μm
0.55 mg/L	2.0 μm	1.8 μm	89%
2.07 mg/L	2.3 μm	1.9 μm	80%

Chamber Environment	Dose levels	
	0.55 mg/L	2.07 mg/L
Chamber Volume	100 liters	100 liters
Airflow	159.29 lpm	5.98 lpm
Temperature ($^{\circ}\text{F}$)	68.1-70.0	68.0-69.4
Relative Humidity (%)	8.6-24.1	13.5-23.0

Clinical Observations: At 0.55 mg/L, clinical signs noted in all test animals were as follows: decreased activity, wobbly gait, congested/shallow/labored breathing, rales, reduced feces, unkempt appearance, rough coat, dark material around the nose/mouth, salivation, hairloss, corneal opacity, low food consumption, hunched posture, exophthalmus, urine stains, and a raised area on one animal's abdominal region.

At 2.07 mg/L, clinical signs noted in all test animals were as follows: decreased activity, wobbly gait, congested/shallow/labored breathing, gasping, few feces, urine stain, unkempt appearance, dehydration, ocular discharge, corneal opacity, constricted pupil, exophthalmus, dark material around nose/mouth, nasal discharge, and low food consumption.

Gross Necropsy Findings: In the 0.55 mg/L group, one survivor had a clear fluid filled cyst found on the right kidney, otherwise there were no significant changes observed.

In the 2.07 mg/L group the following changes were noted: bilateral opacity, lungs dark red, stomach with abnormal contents, black granular mucosa of the stomach, abnormal contents of the small intestine (black/greenish/tan/brown mucoid), liver mottled/pale.

DATA REVIEW FOR SKIN IRRITATION TESTING (§81-5, 870.2500)

Product Manager: Tina Levine, 04
MRID No.: 443885-09

Reviewer: Marianne Lewis
Study Completion Date: 8/28/97
Report No.: 3207.35

Testing Laboratory: Springborn Laboratories, Inc.
Author: D.Douds

Quality Assurance (40 CFR §160.12): Included

Test Material: Taktic E.C.Miticide Insecticide, EPA Reg. No. 54382-3, yellow liquid

Dosage: 0.5 ml
Species: New Zealand White Rabbit
Age: adult
Sex: 6 females
Weight: 2272-2434 g
Source: Myrtle's Rabbitry

Summary:

1. Toxicity Category: II

2. Classification: Acceptable

Procedure (Deviations From §81-5): none

Results: At 1 hour 5/6 had moderate to severe erythema and 1/6 had very slight erythema. At 72 hours 3/6 had moderate to severe and 3/6 had well defined erythema. At 7 days 4/6 had well defined and 2/6 had very slight erythema. Very slight to slight edema was noted in all animals from 1 hour post-exposure to day 7, clearing in all by 10 days. At day 14 3/6 cleared all erythema/edema, 3/6 had well defined to very slight erythema, and 1/6 had very slight edema. Desquamation was seen in all from day 7 until the end of the study. In 2 animals eschar formation was observed (clearing by day 10) and in 2/6 test animals grade 1 blanching & grade 1 superficial lightening was observed (clearing by day 7).

ACUTE TOX ONE-LINER

1. PC CODE: 106201
2. CURRENT DATE: June 12, 1998
3. TEST MATERIAL: Taktic E.C.Miticide Insecticide, EPA Reg. No. 54382-3, amitraz:12.5%

Study/Species/ Lab/Study#/Date	MRID #	Results	Tox. Cat.	Core Grade
acute oral toxicity/rat/ Springborn Labs./3207.31/ 8-28-97	44388505	LD ₅₀ males = 3195 mg/kg females = 2417 mg/kg combined = 2837 mg/kg	III	A
acute dermal toxicity/rabbit/ Springborn Labs./3207.32/ 8-28-97	44388506	LD ₅₀ > 2000 mg/kg	III	A
acute inhalation toxicity/rat/ Springborn Labs./3207.33/ 8-28-97	44388507	estimated LC ₅₀ is >0.55 mg/L	III	A
primary dermal irritation/ rabbit/Springborn Labs./ 3207.35/8-28-97	44388509	At 1 hr. 5/6 had moderate/severe & 1/6 had very slight erythema. At 72 hrs. 3/6 had moderate/severe erythema & 3/6 had well defined erythema. At 7 days 4/6 had well defined and 2/6 had very slight erythema. Very slight to slight edema in all from 1 hr. to day 7. Edema cleared in all by day 10. Desquamation seen in all from day 7 until end of study. Eschar formation, blanching, and superficial lightening also present.	II	A

Core Grade Key:

- A = Acceptable
- S = Supplementary (upgradeable)
- U = Unacceptable
- V = self-Validated

NOTE TO FILE:

There are a few alterations made to the contractor's review of EPA Reg. No. 54382-03, which include: 1) the observations in all studies were reworded, 2) added deviation to acute inhalation study, 3) changed toxicity category for the primary dermal irritation study.

DATE OUT: 30/JAN/1998

SUBJECT: PRODUCT CHEMISTRY REVIEW OF Manufacturing-Use Product[], End Use Product[x]
BARCODE No.: D241308 EPA RECEIVED DATE: 23/SEP/97 REG./File Symbol No.: 54382-3
MRID: 443885-01, 443885-02, & 443885-03 PRODUCT NAME: Taktic E. C.
COMPANY NAME: Hoechst Roussel Vet Action Code: 674

FROM: Paul Horng, Chemist *Paul Horng*
Product Chemistry Team
PRB/SRRD (7508W)

TO: C. P. Moran, CRM
Product Reregistration Branch
PRB/SRRD (7508W)

INTRODUCTION:

With this submission, the applicant, Hoechst Roussel Vet, provided the product chemistry data, CSF, a basic formulation dated 9/SEP/97, a draft label received by the Agency on 23/SEP/97, requesting FIFRA Section 4 reregistration of end-use product Taktic E.C. Reg. No. 54382-3.

FINDINGS:

1. A Reregistration Eligibility Decision (RED), Case # 0234, was issued in November 22, 1996 for the Technical Grade Active Ingredient (TGA) amitraz. The generic data base supporting the reregistration of amitraz has been reviewed and determined to be substantially complete. No data gaps are cited.
2. The submitted product chemistry data (MRIDs 443885-01, -02, and -03) satisfy the data requirements for Guideline Series 61, 62, and 63 (or OPPTS Series 830 Product Properties Test Guidelines). The data are in compliance with 40 CFR 158.155 to 158.190 for reregistration of this end-use product.
3. The submitted CSF, a basic formulation dated 29/SEP/97, is acceptable. All the active and inert ingredients claimed in the CSF are cleared for use in pesticide formulation.
4. Except for the minor revision required for the label, the ingredient statement, the physical/chemical hazard statement, and the storage and disposal statement on the draft label satisfy the requirements of 40 CFR 156.10.

Spec'd { Because amitraz is classified as a "Group C" carcinogen, the Reregistration Eligibility Decision (RED) of amitraz required product's label for the end-use product must be revised to comply with the handler personal protective equipments. To prevent the contact with amitraz from the drifts of livestock spray and splashes from the dipped-animals, the addition of " wear chemical-resistant headgear for overhead exposure" in the paragraph of PPE on product's label is required.

RECOMMENDATION:

The registrant has satisfied the product chemistry data requirements. Once the revision of the label is made, we will have no objection to reregistration of the end-use product, Taktic E.C., Reg. No. 54382-3.

REVIEW OF PRODUCT CHEMISTRY DATA:**PRODUCT NAME: TAKTIC E. C., REG. No. 54382-3****Group A: Series 830-Product Identity, Composition, and Analysis (40 CFR 158.155, .160, .165, .170, .175, and .180).**830-1550 Product Identity and Composition

Refer to CSF.

830-1600 Description of Materials Used to Produce the Product

Refer to CSF.

830-1650 Discussion of Formulation Process

Refer to Confidential Appendix A.

830-1670 Discussion of Formation of Impurities

Refer to Confidential Appendix A.

830-1700 Preliminary Analysis

Refer to Confidential Appendix A.

830-1750 Certified Limits

Refer to Confidential Appendix A.

830-1800 Enforcement of Analytical Method

The Analytical Method (NA-A60) is a Gas Chromatography (GC) method with squalene as an internal standard. The method was validated for use in Subdivision D Product Chemistry studies with Taktic EC. Excellent accuracy and precision were demonstrated. An overall recovery of 100.0% was obtained for the nine formulation replicates ranging in concentration from 9.95% to 14.9% (wt./wt.) with a standard deviation of 0.725%. The analytical method is determined as adequate and support the reregistration of the end-use product.

Group B: Series 830- Physical and Chemical Properties (40 CFR 158.190)

MRID: 443885-03

GUIDELINE REFERENCE NO.(GRN)/TITLE 830-	VALUE OR QUALITATIVE DESCRIPTION /METHOD(S) USED WHERE APPLICABLE AND REFERENCES
-6302 Color	Not required as per PR Notice 92-5.
-6303 Physical States	Clear liquid.
-6304 Odor	Not required as per PR Notice 92-5.
-6314 Oxidation/Reduction: Chemical Incompatibility	The product did not show significant oxidizing or reducing action with the water, zinc, $\text{NH}_4\text{H}_2\text{PO}_4$, KMnO_4 and turpentine.
-6315 Flammability/ Flame Extension	Flash point $40.2 \pm 0.9^\circ\text{C}$ by Pensky-Martens closed cup test.
-6316 Explodability	N/A, product does not possess explosive potential.
-6317 Storage Stability of the Product	No significant change in concentration after 3 month of storage at 40°C .
-6319 Miscibility	N/A, this product is not intended to be diluted with petroleum distillates.
-6320 Corrosion Characteristics	Not corrosive to the electrolytic tin plate in a 7-days test at $40 \pm 1^\circ\text{C}$.
-6321 Dielectric Breakdown Voltage	N/A, product is not to be used around electrical equipment.
-7000 pH	8.54 ± 0.09 for 1% by volume of test substance at $23.03 \pm 0.15^\circ\text{C}$.
-7100 Viscosity	4.7 ± 0.0 cp at 60 rpm and 4.44 ± 0.0 cp at 100 rpm at $25.5 \pm 0.1^\circ\text{C}$.
-7300 Density/Relative Density/ Bulk Density	Density $0.9146 \pm 0.0001 \text{ g/cm}^3$ at $24.9 \pm 0.2^\circ\text{C}$. Bulk density 7.5 lbs / gal.

N/A: not applicable.

Confidential Appendix A

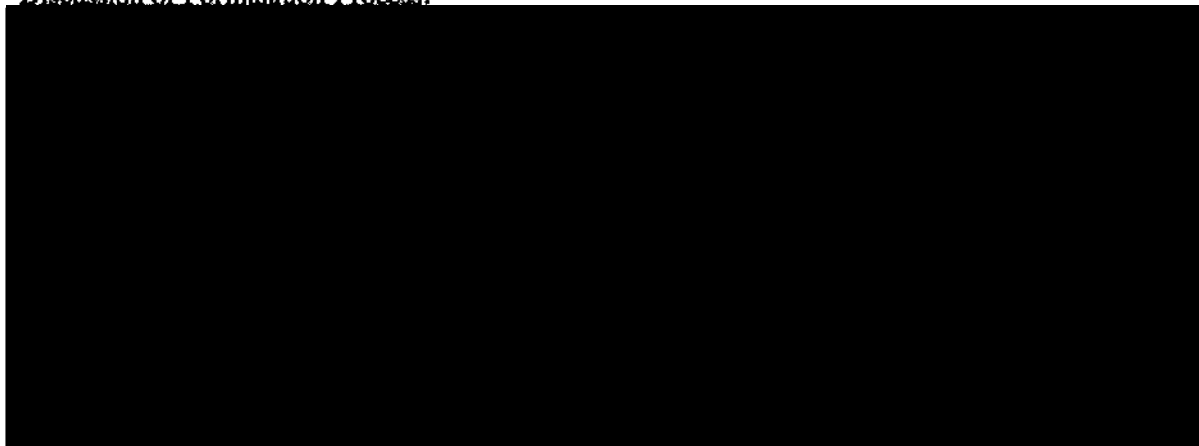
830-1550 Product Identity and Composition.

This end-use product contains 12.5% active ingredient amitraz and 87.5% inert ingredient.

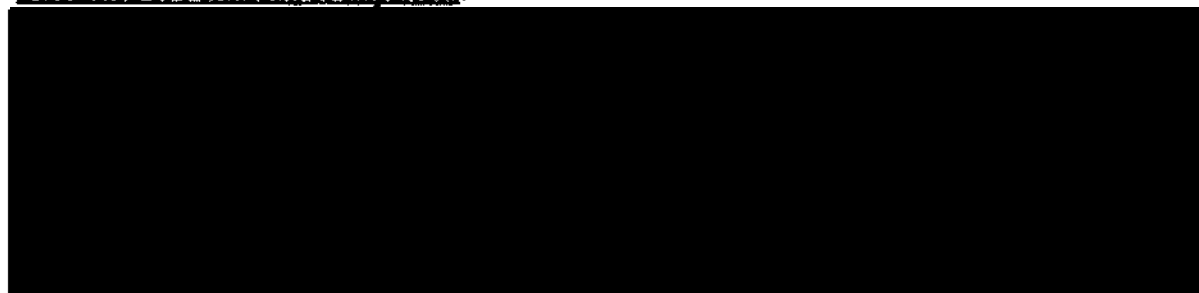
830-1600 Description of Materials Used to Produce the Product.

Refer to the CSF.

830-1650 Discussion of Formulation Process.



830-1670 Discussion of Formation of Impurities.

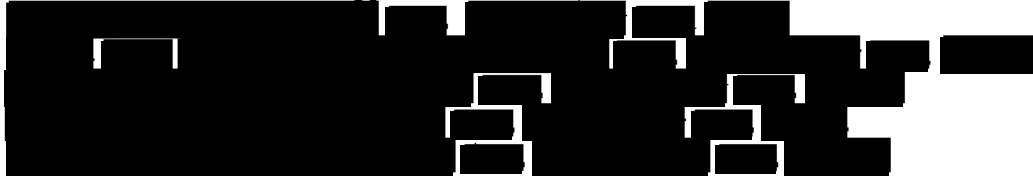


830-1700 Preliminary Analysis.

Five batches of Tactic EC were analyzed in triplicate for the active ingredient amitraz using the Enforcement Analytical Method, the results indicated the mean amitraz concentrations are $12.3 \pm 0.00\%$, $12.5 \pm 0.12\%$, $12.4 \pm 0.17\%$, $12.4 \pm 0.06\%$, and $13.0 \pm 0.10\%$. The overall recovery for the fortification samples was 102%, with an overall standard deviation of 0.814%, and precision of 0.798%. No interferences were noted during the analysis.

830-1750 Certified Limits.

Amitraz: nominal, 12.50%; upper limit, 13.13%; lower limit, 11.88%.





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

9/9/98

MEMORANDUM:

Subject: Tactic ® E.C.
EPA Reg. 54382-03
Re: PRB Preliminary Label assessment

From: John L. Dupuy Ph.D. *JLD 9/9/98*
Product Reregistration Branch
Special Review and Reregistration Division (7508W)

Through Lawrence Schnaubelt *Lawrence Schnaubelt 9/10/98*
Product Reregistration Branch
Special Review and Reregistration Division (7508W)

To: Tina Levine
Branch Chief
Registration Division (7505C)

BACKGROUND: Hoechst Roussel Vet has submitted 5 copies of draft labeling for the subject product in its 8 month response to the Amitraz RED. PRB has completed a preliminary assessment of the draft labeling. In its assessment, PRB has considered the following: 1) Labeling requirements specified in the Amitraz RED; 2) Labeling specified or required in the Product Chemistry and Acute Toxicity Reviews for the subject product; and 3) Labeling requirements as specified in 40 CFR Part 156.10 and associated labeling policy documents such as the Label Review Manual or Pesticide Regulation Notices (PRNs). In addition, PRB has included recommendations to improve the comprehension and consistency of all product labels. A copy of this assessment may be accessed electronically on the Lan through the Q:Drive in Word Perfect. The path is q:\prb\label\054382\003.

NOTE: This preliminary assessment contains recommendations intended to assist Product Managers in their final review of the pesticide label. Product Managers are encouraged to use all or portions of this assessment and then apply their own knowledge of the subject product and the product's regulatory history (including comparison with existing stamped accepted labeling) to conduct a final review of the label. It is the responsibility of the PM to attain the necessary label improvements required for final product reregistration.

SUMMARY OF FINDINGS:

I RED Risk Mitigation:

The subject product label does not contain risk mitigation labeling requirements as specified in the RED.

- * The baseline PPE must be modified.
- * The statement "Follow manufacture's instructions etc." should be placed directly below the PPE.

Refer to Appendix I and III for further details.

II Technical Review Requirements:

Product Chemistry: Based on the Product Chemistry Review by Paul Horng, dated January 30, 1998, the Physical and Chemical Hazards and Storage and Disposal statements cited on the product label are acceptable. The Ingredients labeling must be modified as specified in the Acute Toxicity Review and in Appendix I.

Acute Toxicity: Based on the Acute Toxicity Review by Marianne Lewis dated June 12, 1998, the following changes are required:

- * Ingredient labeling must be modified as specified in Appendix I.

- * The statements appearing under "Statement of Practical Treatment" must be modified as specified in Appendix I.
- * The statements appearing under "Hazards to Humans and Domestic Animals" must be modified as specified in Appendix I.
- * Restricted Use Classification Recommended: Due to eye irritation toxic category I.

Refer to Appendix I for further details.

III Other Labeling Requirements:

The subject product contains the required labeling as specified by 40 CFR Part 156.10, PR Notices and the Label Review Manual except for the following statement.

- * The Statement "Do not apply this product.....etc." must be placed in the Directions for Use. See Appendix I for further details.

Directions for Use:

For purposes of clarity and consistency, PRB recommends that the Registrant make the following changes:

- * The Storage and Disposal text should be enclosed in a box and must be placed under Directions for Use.
- * A sub-title, General Instructions and Information should be placed below the Storage and Disposal box.
- * The Directions for Application should be in a Table Format.

See Appendix I, II, and III for further details.

RECOMMENDATIONS:

The subject product label conforms with the RED, Technical Review and Agency label policies except for the comments specified above, and below in Appendices I, II and III.

Appendix I For the Product Label Tactic ® E.C. EPA Reg.No.54382-03

PRB Label Analysis

Label Requirement	Acceptable	Not Acceptable	Comments/Recommendations
Restricted Use Pesticide		X	PRB recommends that Tactic ® EC be labeled a Restricted Use Pesticide. Refer to Attachment 2. The PM should consider and decide whether this is a Restricted Use Label based on the Acute Toxicity studies(Primary Eye, Toxicity Category I) and Attachment 2.
Product Name	X		
Company Name and Information	X		
Identification Numbers	X		
Ingredients Statement		X	The statement "This product contains xylene-range solvents" must be replaced with "Contains Petroleum Distillate."
(KOROC)	X		
Signal Word	X		
General Heading "Precautionary Statements"			

First Aid		X	<p>The "Statement of Practical Treatment" or First Aid and its text should be placed directly under the heading Precautionary Statements. The Statement of Practical Treatment must be revised as follows:</p> <ul style="list-style-type: none"> * IF IN EYES: Hold eyelids open and flush with steady, gentle stream of water for 15 minutes. Get medical attention. * IF ON SKIN: Wash with plenty of soap and water. Get medical attention. * IF SWALLOWED: Call a physician or Poison Control Center. Do not induce vomiting. Drink promptly a large quantity milk, eggwhites, gelatin solution, or if these are not available, drink large quantities of water. Get medical attention. * IF INHALED: Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical attention. <p>NOTE TO PHYSICIAN:</p> <p>The proposed label should contain:</p> <p>Probable mucosal damage may contraindicate the use of gastric lavage.</p> <p>May pose an aspiration pneumonia hazard.</p>
Hazards to Human and Domestic Animals	X		
Precautionary Statements		X	<p>The Precautionary Statements must be changed to read as follows: Corrosive. Causes irreversable eye damage. Causes skin irritation. Harmful if swallowed or absorbed through the skin or inhaled. Do not get in eyes, on skin or on clothing. Avoid breathing spray mist. Wear goggles or face shield. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. Wash thoroughly with soap and water after handling. Remove contaminated cloathing and wash clothing before reuse.</p>

PPE		X	<p>The PPE must be changed to read as follows:</p> <p>Applicators and other handlers must wear:</p> <ul style="list-style-type: none"> * Chemical-resistant apron over long-sleeved shirt and long pants * Chemical-resistant footwear plus socks * Chemical-resistant gloves * Chemical-resistant headgear for overhead exposure * Chemical-resistant apron when cleaning equipment, mixing, or loading. <p>Refer to the Red(Chapter 5) and Attachment 1</p> <p>The statements "Do not apply this product.....area during application" must be moved and should be placed directly under the statement :</p> <p>"It is a Violation of Federal....." in the Directions for Use. Refer to Appendix III.</p> <p>The statements "For livestock spray.....well-ventilated areas." should be moved to the Directions For Use and placed directly under General Precautions and Restrictions under the sub-header General Instructions and Information. Refer to Appendix III.</p>
User Safety Requirements	X		"Follow manufacturers instructions.....from other laundry" should be placed directly below the PPE section.
Engineering Controls (if required)	N/A		
User Safety Recommendations		X	"User Safety Recommendations" and its text must be enclosed in a box.
Environmental Hazards	X		
Physical and Chemical Hazards	X		
Directions for Use (FIFRA Text, WPS and Storage and Disposal)			
Header "Directions for Use"	X		
Violation of Federal Law Text	X		
WPS Text	N/A		
Non-WPS Text	N/A		

Storage and Disposal		X	The specific directions for Storage and Disposal of the pesticide and its container must appear under the Directions for Use. For clarity and consistency, PRB recommends that the "Storage and Disposal" and its text enclosed in box should be placed directly below the statement "It is a violation of Federal....with its labeling." in the Directions for Use.
Directions for Use (General Instructions and Information)			
General Instructions and Information Sub-Header	X		For clarity and consistency, PRB recommends that the sub-heading General Instructions and Information should be placed directly below the Storage and Disposal statements
Chemigation/Prohibition (if applicable)	N/A		
Spray Drift Labeling (if applicable)	N/A		
General Information (non-site specific information on uses, pests, mixing and loading, tank mixing, etc...)	X		For clarity and consistency, PRB recommends that any non site specific information be placed under the sub-heading General Information.
General Precautions and Restrictions	X		For clarity and consistency, PRB recommends that "Do not use.....or other solvents" be moved from its present position and placed directly under the sub-heading General Precautions and Restrictions.
Direction for Use (Directions for Application)			
Sub-Header: Directions for Application	X		For clarity and consistency, PRB recommends that Directions for Application be placed above the specific sites. In addition the Direction for Applications would be clearer in the Table Format. See Appendix II for an example.
Warranty Information			
Consistency with label instructions	X		
Not false and misleading	X		
General Comments			

APPENDIX II

DIRECTIONS FOR APPLICATION

SITE	TARGET PESTS	DOSE	SPECIAL DIRECTIONS
BEEF, and DAIRY CATTLE	<p>TICKS: *Lone Star Tick (<i>Amblyomma americanum</i>)</p> <p>*Gulf Coast Tick (<i>A. maculatum</i>)</p> <p>*Winter Tick (<i>Dermacentor albipictus</i>)</p> <p>*Brown Dog Tick (<i>Rhipicephalus sanguineus</i>)</p> <p>*American Dog Tick (<i>D. variabilis</i>)</p> <p>*Rocky Mountain Wood Tick (<i>Dermacentor andersoni</i>)</p> <p>*Spinose Ear Tick (<i>Otobius megnini</i>)</p> <p>*Black-legged Tick (<i>Ixodes scapularis</i>)</p> <p>*Tropical Bont Tick (<i>A. variegatum</i>)</p> <p>*Cayenne Tick (<i>A. cajennense</i>)</p> <p>*Cattle Tick (<i>Boophilus annulatus</i>)</p> <p>*Southern Cattle Tick (<i>B. microplus</i>)</p> <p>LICE:</p> <p>*Biting Louse (<i>Haematopinus bovis</i>)</p> <p>*Sucking Lice (<i>Haematopinus eurysternus</i>, <i>Linognathus vituli</i>, <i>Solenopotes capillatus</i>)</p>	760 ml (one can) in 100 gallons of water	<p>Spray: Use up to 2 gallons of spray for a fully grown animal. It is important to wet the animal thoroughly and that the spray penetrates to the skin until run-off.</p> <p>For Lone Star ticks, Cattle ticks, Sucking lice, and Chewing lice, particular attention should be given to the legs, axilla and groin area, udder, tail regions and head including the ears. For Gulf Coast ticks and Ear ticks, treat the head, ears, shoulder area and neck with a low pressure spray. For control of lice, a second treatment 10-14 days later is recommended, to kill lice from hatching.</p> <p>Spray Dip Machine: Use up to 2 gallons of spray for a fully grown animal. It is important to wet the animal thoroughly and that the spray penetrates to the skin until run-off. To control cattle scabies, applications should be made as instructed by USDA, APHIS, VS bulletins. Two treatments, 7-10 days apart are required to control cattle scabies.</p>

SITE	TARGET PESTS	DOSE	SPECIAL DIRECTIONS
	MITES: *Scab and Mange Mites (<i>Chorioptes bovis</i> , <i>Psoroptes ovis</i> <i>Sarcoptes scabiei</i> var. <i>bovis</i>)	760 ml (One can) in 50 gallons of water	Spray: Use up to 2 gallons of spray for a fully grown animal. It is important to wet the animal thoroughly and that the spray penetrates to the skin until run-off. Spray Dip Machine: Use up to 2 gallons of spray for a fully grown animal. It is important to wet the animal thoroughly and that the spray penetrates to the skin until run-off. To control cattle scabies, applications should be made as instructed by USDA, APHIS, VS bulletins. Two treatments, 7-10 days apart are required to control cattle scabies.
	Use Tactic ® solutions within 6 hours of mixing.		
SWINE	Mange Mites and Louse (<i>Sarcoptes scabiei</i> var. <i>suis</i> and <i>Haematopinus suis</i>)	760 ml (one can) in 50 gallons of water ----- Equivalent to ½ fl. ounce per gallon of spray solution	Spray: A sprayer with a coarse nozzle delivering the solution (1/2 fl. ounce per gallon of spray solution) at 70 to 150 psi is recommended. Spray the walls, floor and any fittings in the pen. Spray all animals (at the same time) whether visibly affected or not. Spray the animals until the mixture runs off, paying particular attention to treat the jowls, legs, inside the ears and underside of the body. It is important that the spray penetrates to the skin until run-off. A second treatment is recommended to break the parasites' life cycles. Make the application 7-10 days after first for mite control, and 10-14 days for lice control. Dip: An alternate to spraying young pigs (piglets/weaners) is to dip them in a suitable-sized container. Dip 30 animals and then replace dip wash. Use dip wash to treat premises.
	<p>Important: Remove feed from pen and cover drinking bowls. Remove and destroy bedding. Hose out feces and excess feed. Use Tactic ® solutions within 6 hours of mixing.</p> <p>Restrictions:</p> <p>Do not treat animals more than 4 times per year.</p> <p>Do not apply to swine within three days of slaughter.</p> <p>Do not use Tactic ® E.C. at the same time with any other amitraz containing product.</p>		

Appendix III

Recommended Presentation of Label

RESTRICTED USE PESTICIDE

Product Name

Ingredients.....

EPA Registration and Establishment Numbers

Company Name, Address, Phone Number

Net Contents

KEEP OUT OF REACH OF CHILDREN

SIGNAL WORD

PRECAUTIONARY STATEMENTS

FIRST AID

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

PPE

USER SAFETY RECOMMENDATIONS

ENVIRONMENTAL HAZARDS

PHYSICAL AND CHEMICAL HAZARDS

DIRECTIONS FOR USE

It is a Violation of Federal Law.....

**Do not apply this product in a way.... Only protected handlers
may be in the area....**

STORAGE AND DISPOSAL

GENERAL INSTRUCTIONS AND INFORMATION

General Information (non-site-specific)

General Precautions and Restrictions

DIRECTIONS FOR APPLICATION (site-specific)

Directions for Application

WARRANTY STATEMENT

REQUEST FOR 6(a)(2) SCREEN

DATE: 10/23/97

FROM: Kathleen O'Malley
Information Services Branch
Document Management Section/ISS/IRSD

TO: Bill Burnam (HED - Tox, Onco, Residue, Prod. Chem)
Jerry Blondell (HED - Animal Safety, Human Health)
~~X~~ Ian Blackwell (RD - Products - Acute Tox)
Bill Schneider (BPPD)
Nini Jordan (EPED)
Tim McMahon (AD - Acute Tox)
Srini Gowda (AD - Efficacy)

SRRD Screen?
Note - Per CP Mmm/
SRRD - RD to screen
product for units
SRRD stuff are in
Place to screen Rk
Product Date - 10/24/97
Screen items
for 10/29/97 Mtg.

Attached are copies of transmittal letters and/or study conclusions of recently received 6(a)(2) data submissions. Please screen this information and provide me with the results by hand/mail/fax delivery of this screen cover sheet with your comments to me in Room 216 CM2 (7502C), Fax: 703/305-7670.

IDENTIFICATION NUMBER 44388508
PRODUCT REGISTRATION NUMBER 54382-3
CHEMICAL NAME Amulet - Taktic EC Malicide/Insecticide
DESCRIPTION Primary eye irritation: rabbits

Briefly describe the reported adverse effect: Corneal opacity, permanent eye damage

Does this submission warrant an expedited review? ☒ Yes ☐ No SLP

If yes, explain: Will change precautionary statements 3207.34 for eye irritation. Will change signal word to danger.

Expedited review is appropriate if the results change our regulatory position on this chemical or product. Examples are:

Acute Tox - label change or a change to category

If end point is more sensitive than current basis for regulatory position

Antimicrobial Product Efficacy Failure - Label change: reduced claims or dosage increased

158.134 Flagging Statement is positive

If expedited, recommended timeframe for review:

Other Comments:

8 month response to RED - Product Re-registration

Please respond by

10/28/97 - if possible

Signature

Ian D. Blackwell

10/27/97
Date

REQUEST FOR 6(a)(2) SCREEN

SRHD Screen?
 Stay not in place
 Yes for
 Product RLT for
 Evaluation

DATE: 10/23/97

FROM: Kathleen O'Malley
 Information Services Branch
 Document Management Section/ISS/IRSD

TO: Bill Burnam (HED - Tox, Onco, Residue, Prod. Chem)
 Jerry Blondell (HED - Animal Safety, Human Health)
 X Ian Blackwell (RD - Products - Acute Tox)
 Bill Schneider (BPPD)
 Nini Jordan (EFED)
 Tim McMahon (AD - Acute Tox)
 Srini Govda (AD - Efficacy)

I have for 10/29/97
 Leon Mueky -

Attached are copies of transmittal letters and/or study conclusions of recently received 6(a)(2) data submissions. Please screen this information and provide me with the results by hand/mail/fax delivery of this screen cover sheet with your comments to me in Room 216 CM2 (7502C), Fax: 703/305-7670.

IDENTIFICATION NUMBER 44388610

PRODUCT REGISTRATION NUMBER 54382-3

CHEMICAL NAME Amvix - Tactic E2 Meticide / Insecticide

DESCRIPTION Dermal Sensitization - Bueker Method:

Briefly describe the reported adverse effect:
 Guinea Pig

Topical (Dermal sensitization)

Does this submission warrant an expedited review? ☒ Yes ☐ No

If yes, explain: The label will then display a precautionary statement for dermal sensitization.

Expedited review is appropriate if the results change our regulatory position on this chemical or product. Examples are:

Acute Tox - label change or a change tox category

If end point is more sensitive than current basis for regulatory position

Antimicrobial Product Efficacy Failure - Label change: reduced claims or dosage increased


158.134 Flagging Statement is positive

If expedited, recommended timeframe for review:

Other Comments: Response to be under RLD.

Please respond by 10/28/97 - if possible

Signature: Ian W. Blackwell Date: 10/27/97

(A) 	United States Environmental Protection Agency Office of Pesticide Programs (H7505C) Washington, DC 20460	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input type="checkbox"/> Other	OPP Identifier Number
			166132

Section I

1. Company/Product Number 54382 - 3	2. EPA Product Manager Larry Fried	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Taktic EC Miticide/Miticide	PM#	
5. Name and Address of Applicant (Include ZIP Code) Hoechst Roussel Vet P.O. Box 4915 Warren, NJ 07059 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section II

<input type="checkbox"/> Amendment - Explain below	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - explain below.

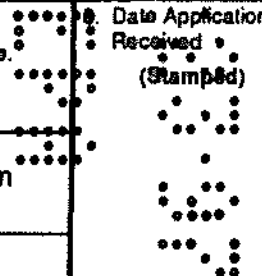
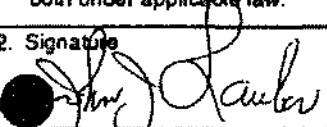
Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Amitraz reregistration - 8 month response

Section III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted.		If "Yes," Unit Package wgt.	No. per container	If "Yes," Package wgt.	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) of Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner In Which Label Is Affixed To Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other (_____)			

Section IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name John J. Lauber, Ph.D.	Title Manager, Product Registration	Telephone No. (Include Area Code) 908/231-3426 908/231-4662 (fax)
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		Date Application Received (Stamped) 
2. Signature 	3. Title Manager, Product Registration	
4. Typed Name John J. Lauber, Ph.D.	5. Date Sept. 16, 1997	



United States Environmental Protection Agency
Washington, DC 20460

Certification with Respect to Citation of Data

Form Approved
OMB No. 2070-0060
Approval Expires 11-30-93

Applicant Name and Address
Hoechst Roussel Vet
P.O. Box 4915
Warren, N.J. 07059

EPA File Symbol/Registration Number
54382-3

Product Name
Taktic Emulsifiable Concentrate Miticide/Insect.

Date of Application
Sept. 16, 1997

NOTE: If your product is a 100% repackaging of another EPA-registered product that you purchase, and is labeled for the same uses, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

1. This application is supported by all data submitted or cited in the application. In addition, if cite-all options are indicated, this application is supported by all data in the Agency's files that concern the properties or effects of this product that is identical or substantially similar, and that is one of the types of data that would be required to be submitted if this application sought the initial registration of a product of identical or similar composition and intended uses under the data requirements in effect on the date of approval of this application. (Check the appropriate boxes, in items 2 and 3 below, that pertain to your application.)

2. I certify that, for each study cited in support of this application for registration that is an exclusive use study,

☒ I am the original submitter*; or

☐ I have obtained the written permission of the original data submitter to cite that study*

3. I certify that, for each study cited in support of this application for registration that is not an exclusive use study:

a. ☐ I am the original data submitter*; or

☐ I have obtained the written permission of the original data submitter to cite that study*; or

b. ☐ I have notified in writing the companies that have submitted data I have cited to support this application and have offered to: (a) Pay compensation for those data in accordance with section 3(c)(1)(D) and 3(c)(2)(D) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA); and (b) Commence negotiations to determine which data are subject to the compensation requirement of FIFRA and the amount and terms of compensation due, if any. The companies I have notified are: (Check one)

☐ All companies listed on the Pesticide Data Submitters List for all active ingredients contained in my product (cite-all method or cite-all option under Selective Method*). (Also, sign the General Offer Statement below.)

☐ Those companies that have submitted the studies which I have cited (Selective method*).

* A Data Matrix identifying these studies is attached. (Note: a Data Matrix is not required under the cite-all method.)

Signature

Name and Title

Date

John J. Lauber, Ph.D.
Manager, Product Registration

Sept. 16, 1997

General Offer to Pay: I hereby offer and agree to pay compensation to other persons, with regard to the approval of this application, to the extent required.

Signature

Name and Title

Date

*Attachment 2***Hoechst** ■**Hoechst Roussel Vet**

30 Independence Blvd. • PO Box 4816 • Warren, New Jersey 07060
Telephone: 908/231-3000

FACSIMILE MESSAGE

TO: Mr. James S. (Steve) Morrill**DATE: July 28, 1998****Tel:**
Fax: 703-308-8041**FROM: Jack Lauber****Tel: (908) 231-3426**
Fax: (908) 231-4462

Subject: Taktic® EC, EPA Reg. No. 64382-3**Dear Mr. Morrill:**

Thank you for your telephone call today concerning Taktic EC.

In Hoechst Roussel Vet's 6-month amitraz reregistration response concerning the labeling for Taktic EC, we requested waivers for the requirements for chemical resistant headgear and coveralls. In Mr. Walter Waldrop's April 13, 1998 letter, he responded to our waiver requests (see attached letter).

Chemical Resistant Headgear – Mr. Waldrop indicated that it would be prudent to retain the use of headgear for overhead exposures. We interpreted this to mean that the Agency was requiring the current label statement, "wear a hat" rather than the more restrictive statement indicated in the amitraz RED, "wear chemical resistant headgear".

Coveralls In lieu of RED requirement for "coveralls over long sleeved shirt and long pants", Mr. Waldrop indicated that the substitute phrase, "chemical resistant apron over long sleeved shirt and long pants" could be used.

During our telephone conversation, we talked also about restricted use classification for Taktic EC. Briefly, we do not feel that restricted use classification is appropriate for Taktic EC. This is because the proposed Taktic EC label states that applicators and other handlers must wear goggles or face shields. The use of goggles or face shields would adequately protect livestock producers, who for the most part, are not certified applicators.

If you have any questions or if I can be of further help, please do not hesitate to call.

Sincerely yours,



John J. Lauber, Ph.D.
Manager, Product Registration

Attachment

980728e

Page 1 of



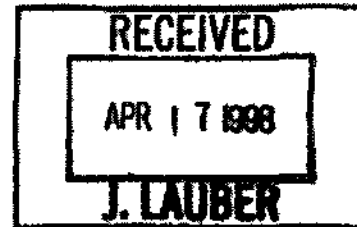
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

Attachment I

APR 13 1998

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

John J. Lauber
Manager, Product Registration
Hoechst Roussel Vet
30 Independence Blvd.
P.O. Box 4915
Warren, NJ 07059



Subject: Amitraz Reregistration
Waiver for Requirement for Coveralls and Headgear
Your letters dated 9/16/97 and 1/28/98

Dr. Lauber:

The Agency has reviewed your requests to waive the requirement for coveralls and headgear for your products registered for use on livestock. Until we receive exposure data to better define the risks associated with use of amitraz to applicators and handlers treating livestock, we believe it prudent to require that end-use product labels retain the use of headgear for overhead exposures. This is especially important for your product Taktic (Reg. No. 54382-3) where, according to your directions for use, walls and any fittings in an animal pen may be treated and may result in overhead exposures.

With regard to the request to waive the requirement for coveralls for the livestock uses, the Agency believes that similar protection would be provided with the use of an apron during application. Thus, in lieu of coveralls over long sleeved shirt and long pants for livestock uses you may substitute with a chemical-resistant apron over long sleeved shirt and long pants.

If you have any questions concerning this letter, please contact Judy Loranger at (703)-308-8056.

Sincerely yours,

Walter I. Waldrop

Walter I. Waldrop, Chief
Reregistration Branch III
Special Review and Reregistration Division

*Attachment 2***Hoechst** ■**Hoechst Roussel Vet**

30 Independence Blvd. • PO Box 4816 • Warren, New Jersey 07059
Telephone: 908/231-2000

FACSIMILE MESSAGE

TO: Mr. James S. (Steve) Morrill**DATE: July 28, 1998****Tel:****FROM: Jack Lauber****Fax: 703-308-8041****Tel: (908) 231-3426****Fax: (908) 231-4462**

Subject: Taktic® EC, EPA Reg. No. 54382-3**Dear Mr. Morrill:**

Thank you for your telephone call today concerning Taktic EC.

In Hoechst Roussel Vet's 8-month amitraz reregistration response concerning the labeling for Taktic EC, we requested waivers for the requirements for chemical resistant headgear and coveralls. In Mr. Walter Waldrop's April 13, 1998 letter, he responded to our waiver requests (see attached letter).

Chemical Resistant Headgear – Mr. Waldrop indicated that it would be prudent to retain the use of headgear for overhead exposures. We interpreted this to mean that the Agency was requiring the current label statement, "wear a hat" rather than the more restrictive statement indicated in the amitraz RED, "wear chemical resistant headgear".

Coveralls In lieu of RED requirement for "coveralls over long sleeved shirt and long pants", Mr. Waldrop indicated that the substitute phrase, "chemical resistant apron over long sleeved shirt and long pants" could be used.

During our telephone conversation, we talked also about restricted use classification for Taktic EC. Briefly, we do not feel that restricted use classification is appropriate for Taktic EC. This is because the proposed Taktic EC label states that applicators and other handlers must wear goggles or face shields. The use of goggles or face shields would adequately protect livestock producers, who for the most part, are not certified applicators.

If you have any questions or if I can be of further help, please do not hesitate to call.

Sincerely yours,



John J. Lauber, Ph.D.
Manager, Product Registration

Attachment

980728e

Page 1 of

3/19/98
L.P.
[Signature]

Hoechst Roussel Vet

Hoechst Roussel Vet
30 Independence Blvd.
P.O. Box 4915
Warren, NJ 07059

Telephone (908) 231-3426
Fax (908) 231-4462
E-mail JLauber@HRVet.com

March 13, 1998

Document Processing Desk (RED-SRRD-0234)
Office of Pesticide Programs (H7504C)
Att. C.P. Moran
Special Review and
Reregistration Division
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460-0001

Subject: Amitraz Reregistration

Dear Mr. Moran:

Thank you very much for faxing me the February 9, 1998 Review of Taktic® EC acute eye irritation and dermal sensitization. I appreciated receiving this information.

As I mentioned in my letter of January 28, 1998 (copy attached), we need guidance from the Agency concerning the required label text for Taktic EC and Point-Guard™ Miticide/Insecticide. The following, requiring Agency acceptance, have a direct bearing on the final label text of these two products:

- coveralls label waiver request
- chemical resistant headgear for overhead exposure label waiver request
- remaining Taktic EC product toxicology studies
- draft labeling

May I hear from you soon concerning this matter? Thank you in advance for your help.

Sincerely yours,

[Signature of John J. Lauber]

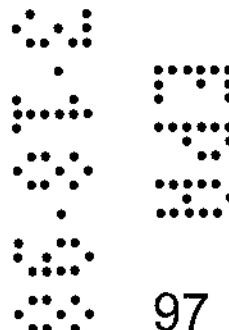
John J. Lauber, Ph.D.
Manager, Product Registration

Attachment

980313b

Hoechst ■

Hoechst Roussel Vet
A member of the Hoechst Group



Hoechst Roussel Vet

Hoechst Roussel Vet
30 Independence Blvd.
P.O. Box 4915
Warren, NJ 07059

Telephone (908) 231-3426
Fax (908) 231-4482
E-mail JLauber@HRVet.com

January 28, 1998

Document Processing Desk (RED-SRRD-0234)
Office of Pesticide Programs (H7504C)
Att. Mr. Walter I. Waldrop
Special Review and
Reregistration Division
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460-0001

Subject: **Amitraz Reregistration**

Dear Mr. Waldrop:

The purpose of this letter is to inquire about the status of the Agency review of the following which have a direct bearing on the labeling of Taktic EC and Point-Guard Miticide/Insecticide required in 1999 by the amitraz RED:

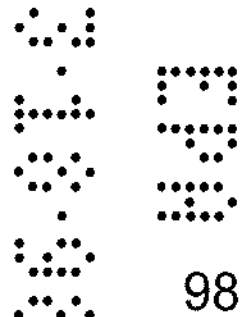
- draft labeling
- coveralls label waiver request
- chemical resistant headgear for overhead exposure label waiver request
- Taktic EC product toxicology studies

Background

Hoechst Roussel Vet (HR Vet) is the registrant of two amitraz products used on cattle and swine. The products are Taktic® Emulsifiable Concentrate Miticide/Insecticide (Taktic EC) (EPA Reg. No. 54382-3) and Point-Guard™ Ready-To-Use Miticide/Insecticide (Point-Guard Miticide/Insecticide) (EPA Reg. No. 54382-6) (Previously Known as Taktic® Linebacker Pour-On).

Hoechst ■

Hoechst Roussel Vet
A member of the Hoechst Group



On September 16, 1997, HR Vet submitted to the Agency draft labeling for Taktic EC and Point-Guard Miticide/Insecticide. As you know, the amitraz RED requires HR Vet to begin to distribute and sell products with revised labeling on or before March 17, 1999. Product with old labeling cannot be distributed or sold. Since HR VET will be producing these products later this year, we need guidance from the Agency concerning required label text.

Draft Labeling

Draft labeling for Taktic EC and Point-Guard were submitted with our letters, dated September 16, 1997 and October 21, 1997. We incorporated all of the required label changes, except for the requirement for the applicators of Taktic EC to wear coveralls and chemical resistant headgear.

Coveralls Label Waiver Request

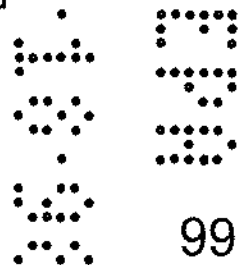
A waiver request for the requirement of coveralls was submitted with our letters dated April 3, September 16 and October 21, 1997. Briefly, our waiver request was based on the fact that the Agency overestimated the exposure to amitraz to farmworkers using Taktic EC, and that minimal personal protective equipment will adequately protect farmworkers from either acute or chronic risk of exposure to amitraz used on livestock.

Chemical Resistant Headgear for Overhead Exposure Label Waiver Request

The requirement for chemical-resistant headgear for overhead exposure is inappropriate for Personal Protective Equipment for both Taktic EC and Point-Guard, as both of these products are not used in an overhead exposure situation.

A Taktic EC label waiver request for the requirement of chemical resistant headgear for overhead exposure was submitted with our letter dated September 16, 1997. This requirement seems applicable to pesticides applied in an orchard crop situation (an overhead exposure situation), and not to the situation with Taktic EC which is a product applied as a spray, dip, or in a spray dip machine for control of ticks, lice and mites on swine and cattle.

A Point-Guard Miticide/Insecticide label waiver request for the requirement of chemical resistant headgear for overhead exposure was submitted with our letters dated September 16 and October 21, 1997. This requirement seems applicable to pesticides applied in an orchard crop situation (an overhead exposure situation).



Point-Guard Miticide/Insecticide is an insecticide applied on swine at a specified dose to control lice and mange mites. Point-Guard Miticide/Insecticide is supplied as a 3000 ml-container which is intended to be carried as a backpack. No water or other liquid is mixed with Point-Guard Miticide/Insecticide. Before application, the 3000 ml-backpack is quickly and easily connected to the applicator gun. The applicator gun has been specially designed and constructed to give continued accurate dosing with the product. The assembled backpack and applicator gun become in effect a "closed system", which does not need to be disconnected for storage. Point-Guard Miticide/Insecticide is directed downwards from the applicator to the pig, and is delivered as a liquid stream, rather than as a spray. Depending upon the size of the pig, only 5 ml to 135 ml of Point-Guard Miticide/Insecticide is delivered to each ear of the pig and along the dorsal midline from between the ears to the rump of the animal. The product is not applied to the entire animal because the Point-Guard Miticide/Insecticide has been specially formulated to spread by itself over the body of the animal after application. Point-Guard application is without product waste, which often occurs when using sprays and dips. Because of Point-Guard's closed application system, there is no mist or spray that the applicator is exposed to.

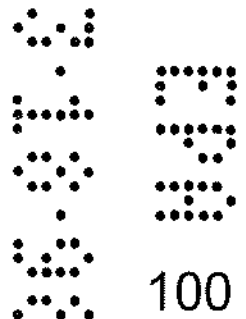
Taktic EC product toxicology studies

The results obtained in the new product toxicology studies for Taktic EC indicated that the product is a severe eye irritant and causes skin sensitization. Consequently, in conformance with 40 CFR 156.10, label changes have been made, including the change in the signal word from "Caution" to "Danger".

In conclusion, we would appreciate learning from the Agency the status of the review of the draft labeling, label waiver requests for coveralls and chemical resistant headgear, and the new Taktic EC product toxicology studies. Thank you in advance for your help.

Sincerely yours,

John J. Lauber, Ph.D.
Manager, Product Registration



Hoechst Roussel Vet

Hoechst Roussel Vet
Route 202-206
PO Box 2500
Somerville, NJ 08876-1258
Telephone (908) 231-2000
Direct line (908) 231-3426

April 9, 1997

Mr. C. P. Moran, Chemical Review Manager
Product Reregistration Branch
Special Review and Reregistration Division (7508W)
Office of Pesticide Programs
Environmental Protection Agency
401 M Street, SW
Washington, DC 20460

Subject: Reregistration Eligibility Decision, Amitraz, Case 0234
90 day response - product specific

Dear Mr. Moran:

Hoechst Roussel Vet (HRV) is the registrant of two amitraz products used on cattle and swine. The products are Taktic® Emulsifiable Concentrate Miticide/Insecticide (Taktic EC) (EPA Reg. No. 54382-3) and Point-Guard™ Ready-To-Use Miticide/Insecticide (Point-Guard Miticide/Insecticide)(EPA Reg. No. 54382-6) (Previously Known as Taktic® Linebacker Pour-On).

On January 17, 1997, HRV received the Amitraz Reregistration Eligibility Decision (RED) by certified mail. As per the instructions that accompanied the RED, we are making our 90-day response (product specific) with this letter and are enclosing the completed "Data Call-In Response" and "Requirements Status and Registrant's Response".

Also, in regard to the Amitraz RED, we are submitting the following under separate cover: a request for waiver of the coveralls label requirement.

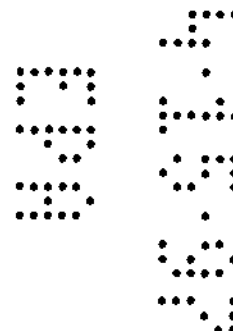
If you have any questions, or require additional information, please do not hesitate to call me at 908-231-3426.

Sincerely yours,



John J. Lauber Ph.D.
Manager, Product Registration

Certified Mail (P 205 871 890), Return Receipt Requested



Hoechst Roussel Vet
A member of the Hoechst Group

Taktic®

EMULSIFIABLE CONCENTRATE MITICIDE/INSECTICIDE

FOR THE CONTROL OF TICKS, MANGE MITES AND LICE ON BEEF
CATTLE, DAIRY CATTLE AND SWINE

DO NOT USE ON HORSES. MAY CAUSE FATAL COLON
IMPACTION.

EPA Reg. No. 54382-3 EPA Est No. 045639-CAN-001
U.S. Patent Nos. 3,781,355 and 3,864,497

Hoechst Roussel Vet

30 Independence Blvd.
Warren, NJ 07059

Hoechst

Hoechst Roussel Vet
A member of the Hoechst Group

ACTIVE INGREDIENT:	Percent by Weight
Amitraz (N'-(2,4-dimethylphenyl)-N- [[2,4-dimethylphenyl]imino]methyl)- N-methylmethanilmidamide)	12.5
INERT INGREDIENTS:	87.5
TOTAL	100.0

This product contains xylene-range solvents.

PRECAUCION AL USUARIO: Si usted no lee Inglés, no use este
producto hasta que la etiqueta haya sido explicado ampliamente.

(TO THE USER: If you cannot read English, do not use this product
until the label has been fully explained to you.)

KEEP OUT OF REACH OF CHILDREN **DANGER-PELIGRO CAUTION-** **PRECAUCION** STATEMENT OF PRACTICAL TREATMENT

IF SWALLOWED: DO NOT INDUCE VOMITING. CALL A PHYSICIAN
OR POISON CONTROL CENTER IMMEDIATELY. IT IS
PREFERABLE TO USE GASTRIC LAVAGE UNDER MEDICAL
SUPERVISION DUE TO ASPIRATION HAZARD. DO NOT INDUCE
VOMITING OR GIVE ANYTHING BY MOUTH TO AN UNCONSCIOUS
PERSON.

AMITRAZ IS NOT AN ORGANOPHOSPHORUS COMPOUND. DO
NOT USE ATROPINE AS AN ANTIDOTE.

IF IN EYES: FLUSH WITH PLENTY OF WATER. GET MEDICAL
ATTENTION IF IRRITATION PERSISTS.

IF ON SKIN: WASH WITH PLENTY OF SOAP AND WATER. GET
MEDICAL ATTENTION IF IRRITATION PERSISTS.

PRECAUTIONARY STATEMENTS

Hazards to Humans (and Domestic Animals)

DANGER CAUTION

Causes eye damage. Do not get in eyes. Harmful if swallowed, inhaled or absorbed through skin. Repeated skin contact may cause an allergic reaction in certain individuals. Avoid breathing vapors or spray mists and avoid contact with skin or clothing.

Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

Harmful if absorbed through skin. Avoid contact with skin, eyes or clothing.

Causes moderate eye irritation.

Personal Protective Equipment (PPE)

Applicators and other handlers must wear:

Long-sleeved shirt and long pants
Chemical-resistant footwear plus socks.
Chemical-resistant gloves
Goggles or face shield, and chemical-resistant apron when cleaning equipment, mixing or loading

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.

For livestock spray or dip applications in enclosed areas: Apply only in well-ventilated areas.

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions exist for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

User Safety Recommendations

- Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

During mixing/loading or application, wear a long-sleeved shirt and long pants. Wear chemical-resistant gloves, a hat, socks, boots, and goggles or face shield. Mixer/loaders should also wear a chemical-resistant apron when handling the concentrated product. Wash thoroughly with soap and water after handling and before eating, urinating or smoking. Remove and wash clothing before reuse. Clothing should be laundered separately from household articles. Replace gloves frequently. Clothing which has been drenched and used gloves should be disposed of in accordance with state or local regulation.

ENVIRONMENTAL HAZARDS

This product- pesticide is toxic to fish and aquatic invertebrates. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean water mark. Drift and runoff from treated areas may be hazardous to fish aquatic organisms in adjacent

~~sites. Do not contaminate water by cleaning of equipment or disposal of equipment when disposing of equipment washwaters or rinsate.~~

PHYSICAL OR CHEMICAL HAZARDS

Do not use or store near heat or open flame.

STORAGE AND DISPOSAL

STORAGE: Not for storage in and around the home environment. Store in original container in a locked dry place. Do not open the container until ready to use. Use entire contents of can when opened. Keep from freezing.

PESTICIDE DISPOSAL: Do not contaminate water, food or feed by storage or disposal. Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of federal law. If these wastes cannot be disposed of by use according to label instructions, contact your state pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

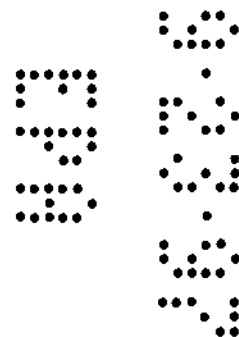
In case of spillage, cover with an absorbent such as soda ash, clay or sawdust. Sweep up and dispose of as directed under Storage and Disposal.

DO NOT REUSE EMPTY CONTAINER.

EMERGENCY PHONE NOS.:

HUMAN, FIRE, SPILLS, ENVIRONMENTAL:
1-800-228-5635, Ext. 132

ANIMALS: 1-800-345-4735, Ext. 104



DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

DO NOT USE ON HORSES or DOGS - CAN CAUSE DEATHS

DO NOT OPEN CONTAINER UNTIL READY TO USE.

USE TAKTIC® E.C. WITH WATER ONLY. DO NOT MIX WITH OIL OR OTHER SOLVENTS.

BEEF AND DAIRY CATTLE

TAKTIC® E.C. can be used on lactating dairy animals, with no withholding period for milk following application. Also, there is no post-treatment slaughter interval on beef and dairy cattle.

TICKS AND LICE:

TAKTIC® E.C. will control the following Ticks and Lice on cattle:

Lone Star Tick (*Amblyomma americanum*)

Gulf Coast Tick (*A. maculatum*)

Winter Tick (*Dermacentor albipictus*)

Brown Dog Tick (*Rhipicephalus sanguineus*)

American Dog Tick (*D. variabilis*)

Rocky Mountain Wood Tick (*Dermacentor andersoni*)

Spinose Ear Tick (*Otobius megnini*)

Black-legged Tick (*Ixodes scapularis*)

Tropical Bont Tick (*A. variegatum*)

Cayenne Tick (*A. cajennense*)

Cattle Tick (*Boophilus annulatus*)

Southern Cattle Tick (*B. microplus*)

Biting Louse (*Damalinia bovis*)

Sucking Lice (*Haematopinus eurysternus*, *Linognathus vituli*,
Solenopotes capillatus)

MITES

Scab and Mange Mites (*Chorioptes bovis*, *Psoroptes ovis* and
Sarcoptes scabiei var. *bovis*)

Spray:

For control of ticks and lice, mix one can (760 ml) of TAKTIC® E.C. in 100 gallons of water; for control of mites, mix one can of TAKTIC® E.C. in 50 gallons of water. Use Taktic® solutions within 6 hours of mixing. Use up to 2 gallons of spray for a fully grown animal. It is important to wet the animal thoroughly and that the spray penetrates to the skin until run-off. For Lone Star ticks, cattle ticks, sucking lice and chewing lice, particular attention should be given to the legs, axilla and groin area, udder, tail regions and head, including the ears. For Gulf Coast ticks and ear ticks, treat the head, ears, shoulder area and neck with a low pressure spray. For control of lice, a second treatment 10-14 days later is recommended, to kill lice hatching from eggs.

Spray Dip Machine:

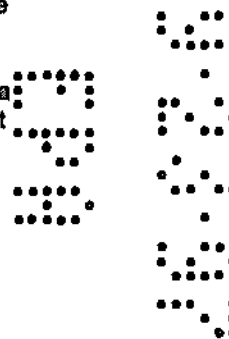
For control of ticks and lice, mix one can (760 ml) of TAKTIC® E.C. in 100 gallons of water; for control of mites, mix one can of TAKTIC® E.C. in 50 gallons of water. To control cattle scabies, applications should be made as instructed by USDA, APHIS, VS bulletins. Two treatments 7-10 days apart are required to control cattle scabies. Use Taktic® solutions within 6 hours of mixing. Use up to 2 gallons of spray for a fully grown animal. It is important to wet the animal thoroughly and that the spray penetrates to the skin until run-off.

SWINE

MANGE MITE AND LOUSE (*Sarcoptes scabiei* var. *suis* and
Haematopinus suis):

IMPORTANT

Remove feed from pen and cover drinking bowls. Remove and destroy bedding. Hose out feces and excess feed. Use TAKTIC® solutions within 6 hours of mixing.



Spray:

Mix one can (760 ml) TAKTIC® E.C. in 50 gallons of water (equivalent to 1/2 fl. ounce per gallon of spray solution). A sprayer with a coarse nozzle delivering the solution at 70 to 150 psi is recommended. Spray the walls, floor and any fittings in the pen. Spray all animals (at the same time) whether visibly affected or not. Spray the animals until the mixture runs off, paying particular attention to treat the jaw, legs, inside the ears and underside of the body. It is important that the spray penetrates to the skin until run-off. A second treatment is recommended to break the parasites' life cycles. Make the application 7-10 days after the first treatment for mite control, and 10-14 days for lice control.

An alternate to spraying young pigs (piglets/weaners) is to dip them in a suitable-sized container. Dip 30 animals and then replace dip wash. Use dip wash to treat premises.

Do not treat animals more than 4 times per year.

Do not apply to swine within three days of slaughter.

Do not use Taktic® E.C. at the same time with any other amitraz containing product.

NET CONTENTS: 760 ml (25.7 fl. oz.)

IMPORTANT NOTICE: DISCLAIMER

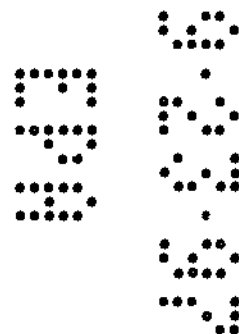
Read "IMPORTANT NOTICE: DISCLAIMER" before buying or using. If terms are not acceptable, return at once unopened. HOECHST ROUSSEL VET warrants only that the product conforms to the chemical description on the label and is reasonably fit for the purpose stated on the label when used in accordance with the directions under normal conditions of use. This warranty does not extend to the use of this product contrary to label instructions or under abnormal conditions, or under conditions not reasonably foreseeable to HOECHST ROUSSEL VET, and user assumes the risk of any such use. HOECHST ROUSSEL VET MAKES NO OTHER WARRANTY, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE OR OF MERCHANTABILITY. In no case shall HOECHST ROUSSEL VET be liable for consequential, special, indirect or incidental damages resulting from the use or handling of this product. The foregoing conditions of sale and warranty can be varied only by an agreement in writing signed by a duly authorized representative of HOECHST ROUSSEL VET.

Taktic® (amitraz) is registered trademark of Hoechst Veterinär GmbH.
The name and logo HOECHST are registered trademarks of HOECHST AG.

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785205-2/97

MADE IN CANADA

Reference: EPA Stamped Accepted Label May 23, 1995; revised as per L. Dulak 5/30/97 e-mail plus amitraz RED.
970827d



Taktic®

EMULSIFIABLE CONCENTRATE MITICIDE/INSECTICIDE

FOR THE CONTROL OF TICKS, MANGE MITES AND LICE ON BEEF
CATTLE, DAIRY CATTLE AND SWINE

DO NOT USE ON HORSES. MAY CAUSE FATAL COLON
IMPACTION.

EPA Reg. No. 54382-3 EPA Est No. 045639-CAN-001
U.S. Patent Nos. 3,781,355 and 3,864,497

Hoechst Roussel Vet

30 Independence Blvd.
Warren, NJ 07059

Hoechst

Hoechst Roussel Vet
A member of the Hoechst Group

ACTIVE INGREDIENT:

Amitraz (N'-(2,4-dimethylphenyl)-N-
[[2,4-dimethylphenyl]imino]methyl]-
N-methylmethanimidamide)

Percent by Weight

12.5

INERT INGREDIENTS:

87.5

TOTAL

100.0

This product contains xylene-range solvents.

PRECAUCION AL USUARIO: Si usted no lee Inglés, no use este
producto hasta que la etiqueta haya sido explicado ampliamente.

(TO THE USER: If you cannot read English, do not use this product
until the label has been fully explained to you.)

KEEP OUT OF REACH OF CHILDREN **DANGER-PELIGRO CAUTION-** **PRECAUCION**

STATEMENT OF PRACTICAL TREATMENT

IF SWALLOWED: DO NOT INDUCE VOMITING. CALL A PHYSICIAN
OR POISON CONTROL CENTER IMMEDIATELY. IT IS
PREFERABLE TO USE GASTRIC LAVAGE UNDER MEDICAL
SUPERVISION DUE TO ASPIRATION HAZARD. DO NOT INDUCE
VOMITING OR GIVE ANYTHING BY MOUTH TO AN UNCONSCIOUS
PERSON.

AMITRAZ IS NOT AN ORGANOPHOSPHORUS COMPOUND. DO
NOT USE ATROPINE AS AN ANTIDOTE.

IF IN EYES: FLUSH WITH PLENTY OF WATER. GET MEDICAL
ATTENTION IF IRRITATION PERSISTS.

IF ON SKIN: WASH WITH PLENTY OF SOAP AND WATER. GET
MEDICAL ATTENTION IF IRRITATION PERSISTS.

PRECAUTIONARY STATEMENTS

Hazards to Humans (and Domestic Animals)

DANGER CAUTION

Causes eye damage. Do not get in eyes. Harmful if swallowed, inhaled or absorbed through skin. Repeated skin contact may cause an allergic reaction in certain individuals. Avoid breathing vapors or spray mists and avoid contact with skin or clothing.

Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

~~Harmful if absorbed through skin. Avoid contact with skin, eyes or clothing.~~

~~Causes moderate eye irritation.~~

Personal Protective Equipment (PPE)

Applicators and other handlers must wear:

Long-sleeved shirt and long pants

Chemical-resistant footwear plus socks.

Chemical-resistant gloves

Goggles or face shield, and chemical-resistant apron when cleaning equipment, mixing or loading

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.

For livestock spray or dip applications in enclosed areas: Apply only in well-ventilated areas.

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions exist for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

User Safety Recommendations

- Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

~~During mixing/loading or application, wear a long-sleeved shirt and long pants. Wear chemical-resistant gloves, a hat, socks, boots, and goggles or face shield. Mixer/loaders should also wear a chemical-resistant apron when handling the concentrated product. Wash thoroughly with soap and water after handling and before eating, urinating or smoking. Remove and wash clothing before reuse. Clothing should be laundered separately from household articles. Replace gloves frequently. Clothing which has been drenched and used gloves should be disposed of in accordance with state or local regulation.~~

ENVIRONMENTAL HAZARDS

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~~sites. Do not contaminate water by cleaning of equipment or disposal of equipment when disposing of equipment washwaters or rinsate.~~

PHYSICAL OR CHEMICAL HAZARDS

Do not use or store near heat or open flame.

STORAGE AND DISPOSAL

STORAGE: Not for storage in and around the home environment. Store in original container in a locked dry place. Do not open the container until ready to use. Use entire contents of can when opened. Keep from freezing.

PESTICIDE DISPOSAL: Do not contaminate water, food or feed by storage or disposal. Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of federal law. If these wastes cannot be disposed of by use according to label instructions, contact your state pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

In case of spillage, cover with an absorbent such as soda ash, clay or sawdust. Sweep up and dispose of as directed under Storage and Disposal.

DO NOT REUSE EMPTY CONTAINER.

EMERGENCY PHONE NOS.:

HUMAN, FIRE, SPILLS, ENVIRONMENTAL:
1-800-228-5635, Ext. 132

ANIMALS: 1-800-345-4735, Ext. 104

DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

DO NOT USE ON HORSES or DOGS - CAN CAUSE DEATHS

DO NOT OPEN CONTAINER UNTIL READY TO USE.

USE TAKTIC® E.C. WITH WATER ONLY. DO NOT MIX WITH OIL OR OTHER SOLVENTS.

BEEF AND DAIRY CATTLE

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Black-legged Tick (*Ixodes scapularis*)

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Cayenne Tick (*A. cajennense*)

Cattle Tick (*Boophilus annulatus*)

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Biting Louse (*Damalinia bovis*)

Sucking Lice (*Haematopinus eurysternus*, *Linognathus vituli*,
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Scab and Mange Mites (*Chorioptes bovis*, *Psoroptes ovis* and
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SWINE

MANGE MITE AND LOUSE (*Sarcoptes scabiei* var. *suis* and
Haematophilus suis):

IMPORTANT

Remove feed from pen and cover drinking bowls. Remove and destroy bedding. Hose out feces and excess feed. Use TAKTIC® solutions within 6 hours of mixing.

Spray:

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Do not treat animals more than 4 times per year.

Do not apply to swine within three days of slaughter.

Do not use Taktic® E.C. at the same time with any other amitraz containing product.

NET CONTENTS: 760 ml (25.7 fl. oz.)

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Taktic® (amitraz) is registered trademark of Hoechst Veterinär GmbH. The name and logo HOECHST are registered trademarks of HOECHST AG.

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785205-2/97

MADE IN CANADA

Reference: EPA Stamped Accepted Label May 23, 1995; revised as per L. Dulak 5/30/97 e-mail plus amitraz REO.
970827d

